FEDERAL REGISTER

Vol. 81 Wednesday,
No. 96 May 18, 2016

Part II

Department of Justice

Drug Enforcement Administration

Superior Pharmacy I and Superior Pharmacy II; Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket Nos. 15–6 and 15–7]

Superior Pharmacy I and Superior Pharmacy II Decision and Order

This is a consolidated proceeding involving two pharmacies located in Tampa, Florida with common ownership. On October 8, 2014, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration issued an Order to Show Cause to Superior Pharmacy, L.L.C. (hereinafter, Superior II), which proposed the revocation of its DEA Certificate of Registration BS9699731, pursuant to which it is authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered location of 5416 Town 'N' Country Blvd. ALJ Ex. 1, at 1 (No. 15–7). The next day, the Deputy Assistant Administrator issued an Order to Show Cause to Superior Pharmacy, L.L.C. (hereinafter, Superior I), which proposed the revocation of its DEA Certificate of Registration BS9255274, pursuant to which it is authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered location of 3007 W. Cypress Street, Suite 1. ALJ Ex. 1, at 1 (No. 15–6).

As grounds for the proposed actions (which also included the denial of any pending applications), the Show Cause Orders alleged that each pharmacy's ''continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.; see also* ALJ Ex. 1, at 1 (No. 15–7); 21 U.S.C. 824(a)(4). Specifically, with respect to each pharmacy, the Orders alleged that their ''pharmacists repeatedly failed to exercise their corresponding responsibility to ensure that controlled substances they dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice'' and that their ''pharmacists ignored readily identifiable red flags that [the] controlled substances prescribed were being diverted and dispensed despite unresolved red flags.'' ALJ Ex. 1, at 1 (No. 15–6); ALJ Ex. 1, at 1 (No. 15–7) (both citing 21 CFR 1306.04(a); *Holiday CVS. L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195,* 77 FR 62315, 62319 (2012)).

The Show Cause Orders further alleged that each pharmacy's ''pharmacists dispensed controlled substances when they knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacist knew or should have known that the controlled substances were abused and/or diverted by the customer.'' ALJ Ex. 1, at 2 (No. 15–6); ALJ Ex. 1, at 2 (No. 15–7). Each Show Cause Order then listed various red flags which each Respondent's pharmacists allegedly failed to resolve before dispensing prescriptions, including: (1) ''Multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor''; (2) ''individuals presenting prescriptions for controlled substances known to be highly abused, such as oxycodone and hydromorphone''; (3) ''individuals paying . . . for controlled substances with cash''; [1] and (4) ''individuals residing long distances from the pharmacy.'' ALJ Ex. 1, at 2 (No. 15–6); ALJ Ex. 1, at 2 (No. 15–7). Each Show Cause Order then set forth allegations of specific instances in which Respondents' pharmacists dispensed oxycodone 30 mg or hydromorphone 8 mg without resolving various red flags presented by the patients and/or the prescriptions; the Order further alleged that several of these prescriptions were facially invalid because they lacked the patient's address. ALJ Ex 1, at 2 (No. 15–6); ALJ Ex. 1, at 2 (No. 15–7).

Each Show Cause Order further alleged that Respondents' pharmacists dispensed hydromorphone, notwithstanding that the ''dosage amounts . . . if taken as directed, far exceeded the recommended dosages of hydromorphone that should be taken on a daily basis.'' ALJ Ex. 1, at 2 (No. 15–6); ALJ Ex. 1, at 3 (No. 15–7). The Superior I Order also alleged that its pharmacists dispensed prescriptions, which were written by the same doctor on the same day, for ''large and substantially similar quantities of'' oxycodone 30 mg, ''to two customers . . . both of whom resided at the same address,'' in a town ''located approximately [449 miles] from'' the pharmacy. ALJ Ex. 1, at 2 (No. 15–6). Likewise, the Superior II order alleged that its ''pharmacists dispensed large and substantially similar quantities of hydromorphone and oxycodone to two individuals with the same last name who received their prescriptions on the same day from doctors at the same clinic.'' ALJ Ex. 1, at 3 (No. 15–7).

In addition, the Superior I Order alleged that the pharmacy ''failed to create and maintain accurate [schedule II order forms] in violation of 21 U.S.C. 842(a)(5),'' and that ''[a]t least two [of its] pharmacists . . . shared a private key (password) for digitally signing'' controlled substances orders, ''in violation of 21 CFR 1311.30(a), (c), and (e).'' ALJ Ex. 1, at 3–4 (No. 15–6). Finally, the Superior I Order alleged that a DEA audit for the period of May 2, 2011 through February 4, 2013 found, *inter alia,* that the pharmacy was short 15,560 dosage units (du) of oxycodone 30 mg; 11,951 du of hydromorphone 8 mg; 946 du of hydromorphone 4 mg; and 864 du of methadone 10 mg. *Id.* at 4.

The Superior II Order alleged that it had also failed to maintain accurate schedule II order forms and had failed to retain copy three of these forms as required by DEA regulations. ALJ Ex. 1, at 3 (No. 15–7) (citing 21 CFR 1305.13(a) & (e); *id.* § 1305.17(a); 21 U.S.C. 827(b)). The Order further alleged that the pharmacy failed to create records of the quantity and date received for orders it placed using the Controlled Substances Ordering System (CSOS) and that it ''also failed to electronically archive and link these records to the original order.'' *Id.* at 4. Finally, the Superior II Order alleged that a DEA audit for the period of July 31, 2012 through February 4, 2013 found, *inter alia,* that the pharmacy had overages of 2,576 du of hydromorphone 8 mg; 1,189 du of oxycodone 30; and 896 du of methadone 10 mg.

The Show Cause Order issued to Superior I was served on October 17, 2014, and the Show Cause Order issued to Superior II was served on October 16, 2014. *See* ALJ Ex. 3 (No. 15–6); ALJ Ex. 4 (No. 15–7). On November 14, 2014, each pharmacy, through its counsel, requested a hearing on the allegations. *See* ALJ Ex. 2 (No. 15–6); ALJ Ex. 3 (No. 15–7). Each matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge (ALJ) Christopher B. McNeil.

The Prehearing Motions and Rulings

On December 3, 2014, the ALJ issued an Order for Prehearing Statements and Setting the Matter for Hearing (hereinafter, Prehearing Order) in each case. *See* ALJ Ex. 5 (No. 15–6); ALJ Ex. 6 (No. 15–7). In each Prehearing Order, the ALJ directed the Government to file its Pre-hearing Statement no later than 2 p.m. on December 22, 2014, and each Respondent to file its Prehearing Statement no later than 2 p.m. on January 5, 2015. ALJ Ex. 5, at 1 (No. 15–

[1] With respect to Superior I, the Show Cause Order stated the red flag as ''individuals paying high prices for prescriptions for controlled substances with cash.'' ALJ 1, at 2 (No. 15–6).

6); ALJ Ex. 6, at 1 (No. 15–7). The Orders also directed the parties to ''[p]rovide the names and current addresses of all witnesses whose testimony is to be presented,'' and that ''[i]f the Respondent's corporate representative intends to testify, the representative must be listed, and a summary of anticipated testimony as described below must be provided.'' ALJ Ex. 5, at 2 (No. 15–6); ALJ Ex. 6, at 2 (No. 15–7). The ALJ's Orders provided the following instruction regarding the summaries of testimony:

> Provide a brief summary of the testimony of each witness, with counsel for the Government to indicate clearly each and every act, omission or occurrence upon which it relies in seeking to revoke the Respondent's Certificate of Registration, and counsel for Respondent to indicate clearly each and every matter as to which Respondent intends to introduce evidence in opposition. The summaries are to state what the testimony will be, rather than merely listing the areas to be covered. The parties are reminded that testimony not disclosed in the prehearing statements or pursuant to subsequent rulings is likely to be excluded at the hearing.

ALJ Ex. 5, at 2 (No. 15–6); ALJ Ex. 6, at 2 (No. 15–7).

The ALJ's Orders also provided that ''[a]ny requests for subpoena[s] are to be filed by 2:00 p.m. E.S.T. on January 12, 2015,'' and that ''[s]ubpoena requests that do not comply with these instructions will be returned to the requestor without further action.'' [2] ALJ Ex. 5, at 4 (No. 15–6); ALJ Ex. 6, at 4 (No. 15–7). The ALJ's Orders further provided that ''[w]henever a party seeks to file any document, motion, exhibit or otherwise communicate in writing with the Administrative Law Judge, the party must provide a true copy of the same to the opposing party, using the contact information shown in the Certificate of Service below . . . [and] [t]he party making such a filing shall include a 'Certificate of Service' stating that a true copy of the submission has been provided to the opposing party, and shall specify the means by which'' this was accomplished. ALJ Ex. 5, at 5–6 (No. 15–6); ALJ Ex. 6, at 5–6 (No. 15–7).

Finally, the ALJ's Orders directed the parties to file their proposed exhibits with his Office no later than 2:00 p.m. on January 12, 2015; it also directed that a copy of the exhibits be served on the opposing party. ALJ Ex. 5, at 2 (No. 15–6); ALJ Ex. 6, at 2 (No. 15–7). The ALJ's Orders further directed that ''[w]hen any party seeks to . . . present proposed exhibits,'' the party must ''timely provid[e] the OALJ with a facsimile copy'' and ''must mail hard copy filings sufficiently in advance of the due date to assure timely receipt by the hearing clerk'' as well as ''that documents are to be filed in triplicate.'' ALJ Ex. 5, at 5–6 (No. 15–6); ALJ Ex. 6, at 5–6 (No. 15–7).

In his Orders, the ALJ also noted that the cases appeared to ''involve common questions of law or fact'' and thus directed the parties to address whether they should be consolidated. ALJ Ex. 5, at 3 (No. 15–6); ALJ Ex. 6, at 3 (No. 15–7). Thereafter, the Government moved to consolidate the cases (as well as two other cases). Respondent opposed the Government's motion.

On December 22, 2014, the Government filed its Prehearing Statements with respect to each pharmacy. In each of these, the Government disclosed that it intended to elicit testimony from an expert regarding his review of ''numerous controlled substance prescriptions filled by Respondent that contained one or more red flags for diversion which Respondent never resolved.'' ALJ Ex. 6, at 3 (No. 15–6); ALJ Ex. 8, at 3–4 (No. 15–7). The Government then identified the same set of seven red flags. ALJ Ex. 6, at 3 (No. 15–6); ALJ Ex. 8, at 3–4 (No. 15–7). With respect to both pharmacies, the Government then set forth the expert's proposed testimony regarding various oxycodone 30 mg prescriptions and the red flags they presented, as well as his proposed testimony regarding the pharmacy's dispensing of large quantities of hydromorphone and the red flags they presented. ALJ Ex. 6, at 4 (No. 15–6); ALJ Ex. 8, at 3–4 (No. 15–7). And with respect to Superior I, the Government also disclosed that the expert ''will also testify about a customer who willingly purchased a prescription for oxycodone . . . that costs 37% more than the same prescription four months earlier,'' and ''that this fact, combined with the fact that the prescription was facially invalid [as it contained] no patient address constituted a red flag for diversion.'' ALJ Ex. 6, at 5 (No. 15–6).

The Government then noticed both Respondents that its expert ''will testify that the facts surrounding the prescriptions listed above constituted red flags for diversion and that there is no evidence that any of the red flags were resolved prior to distributing the controlled substances to the customers.'' *Id.* at 3 (No. 15–6). Finally, it noticed Respondents that its expert ''will testify that . . . Respondent[s'] pharmacists failed to exercise their corresponding responsibility to ensure that prescriptions for controlled substances were issued for a legitimate medical purpose in the usual course of professional practice.'' ALJ Ex. 6, at 3 (No. 15–6); ALJ Ex. 8, at 3–4 (No. 15–7).

On January 5, 2015, each Respondent filed a ''Motion to Compel'' and a ''Motion for Enlargement of Time to File . . . Pre-hearing Statement,'' as well as a Prehearing Statement. ALJ Exs. 9, 10, 11 (No. 15–6); ALJ Exs. 9, 10, 12 (No. 15–7). In their Motions to Compel, each Respondent noted that on February 4, 2013, DEA had executed an Administrative Inspection Warrant at it and sought an Order from the ALJ requiring the Government to disclose the documents and testimony submitted by DEA Investigators to the Federal Magistrate Judge in obtaining the Warrants. ALJ Ex. 10, at 2 (No.15–6); ALJ Ex 10, at 2 (No. 15–7). Each Respondent's Motion to Compel also sought to require the Government to: (1) Provide ''full and complete copies of all computer data seized . . . during the execution of the'' warrant; (2) identify ''all DEA personnel involved in the preparation and execution of the [warrant] and the subsequent review and analysis of the information, records, and data seized''; and (3) provide ''reports of, and the substance of, any statements made to DEA investigators by [Respondent's] staff.'' ALJ Ex. 10, at 5 (No.15–6); ALJ Ex 10, at 5 (No. 15–7).

Each Respondent also sought an extension of the time to file its Prehearing Statement to the end of March 2015 and sought to reschedule the hearing ''to no sooner than June 2015.'' ALJ Ex. 11, at 3 (No. 15–6); ALJ Ex. 9 (No. 15–7). As support for the motions, Respondents argued that since the execution of the warrants, the Government had 20 months to review the records, and that ''[d]uring this time, the information was not available to Respondent.'' ALJ Ex. 11, at 3 (No. 15–6); ALJ Ex. 9, at 3 (No. 15–7). Respondents further argued ''[w]hile a portion of the seized information, most notably the prescriptions, was provided to Respondent[s] in electronic format, the sheer volume of information coupled with the unreasonably short deadlines surrounding the holiday season make analysis of the information by [it] impossible.'' ALJ Ex. 11, at 3 (No. 15–6); ALJ Ex. 9, at 3 (No. 15–7). Respondents further argued that ''due process requires, and good cause exists, for a significant'' extension of the time to file the Prehearing Statements and ''to prepare for a lengthy hearing in'' these

[2] The Order further required that ''[a]ny motion to quash a subpoena must be filed within three working days of receipt of the subpoena request and must be served on the opposing party.'' ALJ Ex. 5, at 4–5 (No. 15–6); ALJ Ex. 6, at 4–5 (No. 15–7).

matters. ALJ Ex. 11, at 3 (No. 15–6); ALJ Ex. 9, at 3 (No. 15–7).

The Government opposed these motions. With respect to the Motions to Compel, the Government argued that in its Prehearing Statements, it had provided a summary of the testimony it intended to elicit as well as a list of the exhibits it intended to offer; the Government also noted that several weeks earlier, it had met with one of Respondents' counsels and that at no time then or since its motion, had Respondents' counsel ''communicate[d] a need for, or request[ed] any'' of the information it sought through the motions. ALJ Ex. 16, at 3 (No. 15–7). The Government further argued that it had fully complied with its disclosure obligations, and that to the extent Respondents were seeking discovery, '' '[t]here is . . . no general right to discovery under either the APA or DEA regulations, but rather only a limited right to receive in advance of the hearing the documentary evidence and summaries of the testimony which the Government intends to rely upon.' '' ALJ Ex. 16, at 4 (No. 15–7) (quoting *Roy E. Berkowitz,* 74 FR 36758, 36760 (2009)). Finally, the Government argued that to the extent Respondents were asserting that they had a right to receive these materials as a matter of due process, ''Respondent[s] ha[d] not even articulated how the requested materials might be relevant to this proceeding.'' ALJ Ex. 16, at 5 (No. 15–7).

Each Respondent filed a Reply to [the] Government's Response to Motion to Compel. ALJ Ex. 27 (No. 15–6); ALJ Ex.18 (No. 15–7). Therein, Respondents contended that they were entitled to the documents as a matter of due process because the Government had represented that one of its proposed witnesses (a Diversion Investigator) would testify regarding his/her interviews with Respondents' staff and that they would be prejudiced if the Government did not provide the ''same.'' ALJ Ex. 27, at 2 (No. 15–6); ALJ Ex. 18, at 2 (No. 15–7). Respondents further asserted that the ''information is essential,'' because the Government intended to put on evidence that the prescriptions raised red flags and that ''Respondent[s] fail[ed] to exercise [their] corresponding responsibility to resolve the 'red flag[s],' '' and the Government ''has not identified one patient or doctor related to the prescriptions allegedly containing unresolved red flags.'' ALJ Ex. 27, at 2 (No. 15–6); ALJ Ex. 18, at 2 (No. 15–7).

The Government also opposed Respondents' Motions for Enlargement of Time. ALJ Ex. 16, at 6 (No. 15–7). The Government argued that the Show Cause Orders and Prehearing Statements had ''specifically outlined'' the allegations, ''as well as the approximate number of documents it intend[ed] to introduce into evidence.'' *Id.* The Government further argued that it was ''patently specious'' for Respondents ''[t]o characterize this matter as something much more voluminous and complicated than what it is and, as a result, argue that further delay is necessary.'' *Id.* The Government also contended that to the extent Respondents were seeking an extension to review records and prescriptions beyond those referenced in the Show Cause Orders and its Prehearing Statements, those documents were not ''material to the allegation that he [sic] unlawfully dispensed to customers identified in the OTSC and Government's Prehearing Statement.'' *Id.* at 6–7.

On January 5, 2015, the ALJ denied Respondents' Motions for Enlargement. ALJ Ex. 11, at 3 (No. 15–7); ALJ Ex. 12, at 4 (No. 15–6). The ALJ specifically noted ''that since at least October 16, 2014, Respondent[s] ha[ve] been informed of the nature of the charges presented in the Order to Show Cause,'' and that in their motions, Respondents had acknowledged that the Government had provided them with the prescriptions. ALJ Ex. 11, at 3 (No. 15–7); ALJ Ex. 12, at 3 (No. 15–6). The ALJ explained that neither Respondent had ''established that it has been prevented from evaluating those prescriptions identified in the Order to Show Cause [or] that it has been prevented from preparing its prehearing statement.'' ALJ Ex. 11, at 3 (No. 15–7); ALJ Ex. 12, at 3 (No. 15–6). The ALJ also explained that Respondents had known since the issuance of his Prehearing Orders that they were required ''to object to any term of that Order by not later than December 10, 2014,'' and that they failed to object to the orders until the day their Prehearing Statements were due. ALJ Ex. 11, at 3 (No. 15–7); ALJ Ex. 12, at 3 (No. 15–6). The ALJ thus concluded that:

> I am compelled to consider the nature of the allegations, which if proved suggest Respondent[s'] ability to fill controlled substance prescriptions would be inconsistent with the public interest. I am further compelled to consider Respondent[s'] own role in attempting to delay th[ese] proceeding[s], given that [they] failed to timely object to the deadlines set forth in the Order[s]. I am further compelled to consider fairness to all parties, and the convenience of witnesses now identified by the Government in its timely prehearing statement[s]. I am further compelled to consider the need for orderly and prompt administration of justice. All of these considerations compel my finding that good cause has not been shown for either enlarging the time for Respondent[s] to file [their] prehearing statement[s], or for continuing the hearing now set to being on January 27, 2015.

ALJ Ex. 11, at 3 (No. 15–7); ALJ Ex. 12, at 3 (No. 15–6).

The same day (according to OALJ date stamps), each Respondent filed its Prehearing Statement. ALJ Ex. 9 (No. 15–6); ALJ Ex. 12 (No. 15–7). Each Respondent proposed as witnesses ''[a]ny and all patients whose prescriptions were seized . . . pursuant to the Administrative Inspection Warrant executed [on] February 4, 2013 or whose prescriptions for controlled substances were dispensed between January 1, 2011 and February 4, 2013.'' ALJ Ex. 9, at 3 (No. 15–6); ALJ Ex. 12, at 3 (No. 15–7). Respondent Superior I further attached a list of 2,355 purported patients, ALJ Ex. 9, at Attachment A (No. 15–6); and Respondent Superior II attached a list of 2,253 purported patients. ALJ Ex. 12, at Attachment A (No. 15–7). As for the required summary of anticipated testimony, each Respondent proposed that:

> These patients will each be asked to provide testimony regarding their medical history, injuries and related pathology, interactions with treating physicians and dispensing pharmacists, effectiveness of the prescribed controlled substances, continuity of treatment, their reasons for patronage of Superior Pharmacy, LLC . . . such other testimony relevant to the Government's allegation that any of these prescriptions raised 'red flags' which should have caused pharmacists to refuse to dispense the prescribed controlled substances.

ALJ Ex. 9, at 4 (No. 15–6); ALJ Ex. 12, at 4 (No. 15–7).

Respondents further proposed as witnesses ''[a]ny and all physicians who issued the prescriptions seized . . . pursuant to the Administrative Inspection Warrant[s] . . . or whose prescriptions for controlled substances were dispensed at [them] between January 1, 2011 and February 4, 2013,'' as well as ''[a]ny and all physicians who issued prescriptions for controlled substances to the patients identified . . . above after February 4, 2013.'' ALJ Ex. 9, at 3 (No. 15–6); ALJ Ex. 12, at 3 (No. 15–7). Each Respondent attached a list of several hundred physicians who had purportedly issued the controlled substance prescriptions dispensed by them. ALJ Ex. 9, at Attachment B (No. 15–6); ALJ Ex. 12, at Attachment B (No. 15–7). As for the anticipated testimony of the physicians, Respondents represented that:

> These physicians will confirm they performed adequate and appropriate physical examinations of the patients to whom they

issued prescriptions for controlled substances, communication with the dispensing pharmacies regarding such prescriptions, the reasonableness and necessity of the prescriptions to control the pain or other complaints of their patients as required by the standard of care and Florida statutes.

ALJ Ex. 9, at 4 (No. 15–6); ALJ Ex. 12, at 4 (No. 15–7).

Next, Respondents proposed as witnesses ''[a]ny and all pharmacists who dispensed prescriptions for controlled substances to the patients identified . . . above *after* February 4, 2013.'' ALJ Ex. 9, at 3 (No. 15–6); ALJ Ex. 12, at 3 (No. 15–7) (emphasis added). As for their anticipated testimony, Respondents represented that ''[t]hese pharmacists will describe the information they obtained from the patients, physicians and other sources in order to resolve 'red flags,' if any, raised by the described prescriptions for controlled substances.'' ALJ Ex. 9, at 5 (No. 15–6); ALJ Ex. 12, at 5 (No. 15–7). Respondent did not, however, provide the names of any of the pharmacists. ALJ Ex. 9, at 3 (No. 15–6); ALJ Ex. 12, at 3 (No. 15–7).

Respondents also proposed as a witness Mr. Sam Badawi, a pharmacist and attorney. ALJ Ex. 9, at 3 (No. 15–6); ALJ Ex. 12, at 3 (No. 15–7). As for Mr. Badawi's anticipated testimony, Respondents represented that he:

> will testify regarding his qualifications as an expert in the field of pharmacy and the legal and ethical responsibilities of the pharmacists dispensing prescriptions at [each Respondent], the procedures used at [each Respondent] to consider and resolve 'red flags,' inventory, ordering and CSOS compliance issues. Mr. Badawi will further testify that he had reviewed the prescriptions at issue, the relevant inventory and ordering records and prepared summaries of the prescription dispensing activity at [each pharmacy] during 2011 and 2012, and identified significant errors in the inventory performed by the DEA.

ALJ Ex. 9, at 6 (No. 15–6); ALJ Ex. 12, at 6 (No. 15–7).

Respondents further proposed as a witness Mr. Jack Crowley of Gates Healthcare Associates. Respondents represented that Mr. Crowley:

> will testify regarding his knowledge and experience in the investigation, preparation and execution of Administrative Inspection Warrants and the subsequent investigation required. [He] will testify regarding errors in the audits performed by the agents/investigators involved in the investigation of [Respondents]. [He] reviewed the prescriptions, inventory and CSOS records of [Respondents]. [He] will further testify regarding [Respondents'] procedure[s] for resolving potential 'red flag' issues and compliance with recordkeeping requirements related to inventory records, DEA–222 order forms and CSOS issues.

ALJ Ex. 9, at 5 (No. 15–6); ALJ Ex. 12, at 5 (No. 15–7).[3]

On January 9, 2012, each Respondent filed a motion to enlarge the time for filing its proposed exhibits or to alternatively provide its proposed exhibits electronically, as well as a motion to enlarge the time to file its requests for subpoenas. ALJ Ex. 22 (No. 15–6); ALJ Ex. 23 (No. 15–7). In its motion, Superior I explained that its ''Prehearing Statement identifies four categories of proposed exhibits which consist of 23,032 documents,'' of which ''20,925 pages represent the documents seized, and provided to Respondent electronically, by the DEA.'' ALJ Ex. 22, at 2 (No. 15–6). Superior I explained that to comply with the ALJ's Prehearing Order, which required that three copies of each exhibit be filed with the OALJ and one copy be filed with opposing counsel, this would require more than 92,000 pages and ''approximately nineteen standard boxes of paper, which is approximately 950 pounds.'' *Id.* Superior I further explained that because of the volume of copying needed to comply with the Prehearing Order, the documents would have to be sent ''to a third party for reproduction'' and ''the reproduction cannot be completed in the allotted time.'' *Id.* at 3. As for its subpoena requests, Superior I contended that the ALJ's Prehearing Order was ambiguous ''as to whether the requests and completed subpoenas are to be filed in triplicate with the Hearing Clerk,'' and because it was seeking to subpoena 2,861 witnesses, it ''cannot complete the . . . requests . . . with the completed subpoenas using the required template in the allotted time.'' *Id.*

Superior II made similar assertions to Superior I, noting that its proposed exhibits ''consist of 32,123 documents,'' of which ''30,441 pages represent the documents seized, and provided to [it] electronically, by the DEA,'' and that to comply with the ALJ's Prehearing Order, it would have to provide more than 128,000 pages of documents, and require ''approximately 1,300 pounds'' of paper. ALJ Ex. 23, at 2 (No. 15–7). As did Superior I, Superior II asserted that it would have to use a third-party to perform the necessary copying, which could not ''be completed in the allotted time.'' *Id.* at 3. Superior II also asserted that it could not complete the 2,549 subpoena requests for its proposed witnesses on time. *Id.*

On January 12, 2015, each Respondent submitted a letter (dated Jan. 9) to the Hearing Clerk along with thumb drives which contained ''the images of each of the exhibits in [its] Prehearing Statement.'' ALJ Ex. 24 (No. 15–6); ALJ Ex. 24 (No. 15–7). Each Respondent's letter also advised that the paper copies of the subpoena requests would be hand delivered on Monday, January 12, 2015, and on that date, the ALJ ''received more than 3,000 written requests for the issuance of subpoenas in the[] two cases.'' Tr. 18; *see also* ALJ Ex. 24 (No. 15–6); ALJ Ex. 24 (No. 15–7). According to the ALJ, neither Respondent provided ''a certificate of service establishing that [they] ha[d] provided the Government with a true copy of these requests.'' Tr. 18.

The same day, the ALJ's Law Clerk sent a letter under his own signature to each Respondent's Counsel noting that the OALJ had received the thumb drives. ALJ Ex. 28 (No. 15–6); ALJ Ex. 28 (No. 15–7). The Law Clerk then explained that he was returning the thumb drives to each Respondent's counsel because ''[t]he submission of the thumb drive does not adhere to the'' ALJ's Prehearing Order of December 3, 2014. ALJ Ex. 28 (No. 15–6); ALJ Ex. 28 (No. 15–7).

On January 12, the ALJ denied each Respondent's Motion to Compel. The ALJ noted that in the case of *Edge Pharmacy* (Docket No. 15–3), the respondent had sought to compel the disclosure of much of the same material as sought by Superiors I and II. ALJ Ex. 29, at 4 (No. 15–6); ALJ Ex. 29, at 4 (No. 15–7). The ALJ further noted that in *Edge,* the Chief Administrative Law Judge (CALJ) had denied the motion of the respondent on the ground that it did ''not comport with the narrowly-focused grant of authority in 21 CFR 1316.52(d),'' and that the respondent did ''not seek to compel . . . the class of documents discoverable under the [Administrative Procedure Act] or subject to inspection under DEA regulations.'' ALJ Ex. 29, at 4 (No. 15–6); ALJ Ex. 29, at 4 (No. 15–7). As for the reports and the substance of any statements made by Respondents' staff to the Agency's Investigators, the ALJ also found that the CALJ's reasoning applied to these materials. ALJ Ex. 29, at 4 (No. 15–6); ALJ Ex. 29, at 4 (No. 15–7). The ALJ thus concluded that each Respondent had failed to establish its entitlement to the documents. ALJ Ex. 29, at 4 (No. 15–6); ALJ Ex. 29, at 4 (No. 15–7).

[3] Respondents also proposed as witnesses each person ''who participated in the preparation of the application for the Administrative Inspection Warrant[s],'' as well as each person ''who participated in the execution of the Administrative Inspection Warrant[s].'' ALJ Ex. 9, at 3–4 (No. 15–6); ALJ Ex. 12, at 3–4 (No. 15–7).

The same day, in the Superior I matter, the Government submitted its request for the issuance of subpoenas for four witnesses, and in the Superior II matter, the Government submitted its request for the issuance of subpoenas for five witnesses, all of whom had been previously identified in the respective Prehearing Statement.[4] ALJ Ex. 25, at 1–2 (No. 15–6); ALJ Ex. 25, at 1–2 (No. 15–7). The Government also submitted its proposed exhibits in each matter. Docket Sheet, at 2 (No. 15–6); Docket Sheet, at 2 (No. 15–7).

The Government's Motions To Consolidate

On January 13, 2015, the Government moved to consolidate the cases, along with a third matter (Jet Pharmacy). ALJ Ex. 31 (No. 15–6); ALJ Ex. 31 (No. 15–7). In its motions, the Government argued that there were common issues of law and fact with respect to the pharmacies, noting that it intended to call the same expert in each of the cases and each Respondent had stated that it intended to call the same two experts. ALJ Ex. 31, at 2–3 (No. 15–6); ALJ Ex. 31, at 2–3 (No. 15–7). The Government further argued that the expert's testimony would ''account for the bulk of the Government's and likely the Respondents' cases in terms of length of testimony,'' and that consolidation would ''result in a tremendous conservation of time and resources by allowing the Government to present its expert's testimony in one proceeding rather than in three separate proceedings.'' ALJ Ex. 31, at 5 (No. 15–6); ALJ Ex. 31, at 5 (No. 15–7).

The Government also argued that, although ''each of the Respondent pharmacies is a separate business entity, there are also strong indications of common ownership, management, and/or control between the Respondents,'' and that Superior I and II ''are both owned and operated by Victor Obi-Anadiume.'' [5] ALJ Ex. 31, at 3 (No. 15–6); ALJ Ex. 31, at 3 (No. 15–7). As support for this assertion, the Government attached to its motions various documents it obtained from the Florida Department of Heath showing that Victor Obi owned both Superior I and II. The Government thus maintained that consolidation was warranted ''because the conduct of one Respondent may be imputed to other Respondents if it can be shown that the same individuals responsible for misconduct at one pharmacy also managed and/or controlled other pharmacies.'' ALJ Ex. 31, at 5 (No. 15–6); ALJ Ex. 31, at 5 (No. 15–7).

Each Respondent filed identical oppositions to the Government's motions. *See* ALJ Ex. 30 (No. 15–6); ALJ Ex. 32 (No. 15–7). Therein, Respondents argued that ''it is not . . . sufficient for two (2) actions to have a common defendant or one common issue of law'' and that ''other considerations are necessary such as whether maintaining separate actions would lead to inconsistent rulings on similar issues of fact and law and to ensure that the same standard is applied to the determination of such issues as they arise in each case.'' ALJ Ex. 30, at 3–4 (No. 15–6); ALJ Ex. 32, at 3–4 (No. 15–7) (citation omitted). Respondents also argued that consolidation of the cases ''may cause unnecessary confusion for the fact finder and prejudice to the parties.'' ALJ Ex. 30, at 4 (No. 15–6); ALJ Ex. 32, at 4 (No. 15–7) (citation omitted).

Respondents then maintained that ''because each prescription represents a different pattern of facts, it appears there is no overlapping factual issue between the two matters,'' and ''[a]s such, there is no risk of inconsistent results'' which would support consolidation. ALJ Ex. 30, at 5 (No. 15–6); ALJ Ex. 32, at 5 (No. 15–7). Respondents further maintained that ''there is a high risk that one defendant could be prejudiced by evidence relating to another defendant.'' ALJ Ex. 30, at 5 (No. 15–6); ALJ Ex. 32, at 5 (No. 15–7). Respondents also asserted that consolidation would not promote judicial economy ''[b]ecause of the large number . . . and limited overlap of'' the witnesses and because ''the time necessary to complete the hearing as to both parties could exceed ninety (90) days.'' ALJ Ex. 30, at 6 (No. 15–6); ALJ Ex. 32, at 6 (No. 15–7).

On January 15, 2015, each Respondent filed a further pleading, which appear to be identical, on the issue of consolidation. ALJ Ex. 40 (No. 15–6); ALJ Ex. 40 (No. 15–7). In addition to the arguments they previously raised, Respondents contended that ''[t]o the extent the government seeks to rely on a single expert to prove its case in all three matters, it heightens the risk of confusion or attempts to conflate issues between three distinct defendants.'' ALJ Ex. 40, at 6 (No. 15–6); ALJ Ex. 40, at 6 (No. 15–7). They also argued that ''although Respondent[s] share Mr. Obi as a common owner, [he] is not responsible for the day-to-day operations or the implementation of policies and procedures at these separate businesses'' as each pharmacy had a ''different pharmacy manager[ ].'' ALJ Ex. 40, at 7 (No. 15–6); ALJ Ex. 40, at 7 (No. 15–7). Respondents further contended that ''Mr. Obi did not dispense medication or otherwise process prescriptions at these pharmacies during all relevant time periods described in the Orders to Show Cause.'' ALJ Ex. 40, at 7 (No. 15–6); ALJ Ex. 40, at 7 (No. 15–7).

On January 21, 2015, the ALJ granted the Government's motions with respect to Superior I and Superior II. ALJ Ex. 1 (No. 15–6 & 15–7). The ALJ specifically found that ''the Government ha[d] demonstrated the presence of common questions of law and fact with respect to Superior I and Superior II, and ha[d] shown the need to take steps to avoid unnecessary cost or delay.'' *Id.* at 7. More specifically, the ALJ found that the Show Cause Orders ''set forth substantially similar factual claims'' in that ''pharmacists at both pharmacies dispensed controlled substances under conditions where the pharmacists knew or should have known that the controlled substances were being either diverted or abused by those who received the substances.'' *Id.* The ALJ further found that ''[i]n both cases, the [Government] alleged the pharmacists filled prescriptions notwithstanding red flags relating to the unusual distance the patients traveled to have their prescriptions filled, and notwithstanding red flags relating to evidence that the patients were filling multiple prescriptions which bore no address for the patients.'' *Id.*

The ALJ also rejected Respondents' contention that there was ''a substantial risk of prejudice to Respondents in either case.'' *Id.* at 8. The ALJ specifically found that ''the prospect of hearing from the fact and expert witnesses in both cases will reduce the risk of inconsistencies like those that could arise through separate hearings.'' *Id.* The ALJ also ''expressly rejected'' Respondent's contention that there was a heightened ''risk of confusion'' because the Government intended to use the same expert to prove its case, explaining that ''[o]ne expert can easily address the conduct attributed to pharmacists working at these two pharmacies.'' *Id.* Finally, the ALJ reasoned that ''[g]iven there is at least some showing of common ownership, the Government should be, and will be, permitted to advance its theory that 'the conduct of one Respondent may be imputed to [the] other Respondent[ ] if it can be shown that the same individuals responsible for misconduct at one pharmacy also managed and/or controlled other pharmacies.''' *Id.* (citation omitted). The ALJ thus ordered that the cases against Superior I and

[4] The Government also served a copy of both subpoena requests on each Respondent. ALJ Ex. 25, at 2 (No. 15–6); ALJ Ex. 25, at 2 (No. 15–7).

[5] Mr. Obi-Anadiume is also referred to as Mr. Obi throughout this decision.

Superior II be consolidated under Docket No. 15–6. *Id.*

The Government's Motions *in Limine*

On January 15, 2015, the Government also filed a Motion *in Limine* in each matter. Therein, the Government argued that Respondents had failed to comply with the ALJ's Pre-hearing Orders in that they failed to provide adequate summaries of the testimony of their proposed witnesses. With respect to Mr. Badawi, Respondents' proposed expert in pharmacy practice, the Government argued that Respondents' Prehearing Statements ''state[d] no facts or conclusions which, if proven, would rebut any allegations that the Government has made in its OTSC[s] or Prehearing statement[s].'' ALJ Ex. 36, at 4 (No. 15–6); ALJ Ex. 36, at 4–5 (No. 15–7). The Government specifically argued that while ''Respondent[s] state[d] that Mr. Badawi ha[d] 'prepared summaries' of prescription activity and identified 'errors' in DEA inventory[,] [they] fail[ ] to disclose what those summaries entail or what errors have been discovered.'' ALJ Ex. 36, at 4–5 (No. 15–6); ALJ Ex. 36, at 5 (No. 15–7). The Government further argued that Respondents had ''also failed to identify a single 'procedure used at [the pharmacies] to consider and resolve alleged 'red flags,' inventory, ordering and CSO[S] compliance issues.'' ALJ Ex. 36, at 5 (No. 15–6); ALJ Ex. 36, at 5 (No. 15–7). The Government also argued that ''notably absent from [the] Prehearing Statement[s] is any notice that Mr. Badawi will opine that any of the prescriptions identified in the [Show Cause Orders] and the Government's Prehearing Statement[s] were issued in compliance with federal or state law.'' ALJ Ex. 36, at 5 (No. 15–6); ALJ Ex. 36, at 5 (No. 15–7).

As for Respondents' disclosures pertaining to the testimony of Mr. Crowley, the Government argued that ''no facts [were] proffered to give [it] any notice regarding [his] conclusions regarding audit errors, or the basis for those conclusions, should they exist.'' ALJ Ex. 36, at 5 (No. 15–6); ALJ Ex. 36, at 5 (No. 15–7). The Government also argued that while Respondents proposed that this witness would testify regarding their procedures for resolving red flags and complying with other requirements, Respondent had not ''offer[ed] a single fact or detail to describe, identify, or explain that procedure.'' ALJ Ex. 36, at 5 (No. 15–6); ALJ Ex. 36, at 5 (No. 15–7). The Government further contended that it is unclear whether this witness's proposed testimony would discuss the procedures in place during the period of the alleged misconduct or as to procedures subsequently instituted. ALJ Ex. 36, at 6 (No. 15–6); ALJ Ex. 36, at 6 (No. 15–7). Finally, the Government argued that Respondents' disclosure was ''void of any detail about the information [this witness] reviewed to form his opinions about the DEA audits or the procedures Respondents employed at their pharmacy.'' ALJ Ex. 36, at 6 (No. 15–6); ALJ Ex. 36, at 6 (No. 15–7).

Addressing Respondents' proposed taking of the testimony of the numerous patients who filled controlled substance prescriptions at Respondents, the Government maintained that Respondents' disclosure ''constitute[d] a wholesale failure to describe 'each and every matter as to which [they] intend[ed] to introduce evidence in opposition,' '' as required by the ALJ's Pre-hearing Order. ALJ Ex. 36, at 6 (No. 15–6); ALJ Ex. 36, at 6 (No. 15–7). As for the physicians who wrote the prescriptions, the Government argued that the disclosures were inadequate because ''Respondent[s] merely indicate[ ] that these unknown individuals will testify regarding 'communication[s] with the dispensing pharmacists regarding such prescriptions,'' and ''no facts about any such communications are revealed.'' [6] ALJ Ex. 36, at 6 (No. 15–6); ALJ Ex. 36, at 6 (No. 15–7).

The Government also contended that testimony and documentation regarding prescriptions which it did not intend to offer into evidence was irrelevant. ALJ Ex. 36, at 8 (No. 15–6) ALJ Ex. 36, at 8 (No. 15–7). Finally, with respect to the physicians who issued prescriptions filled by Respondents after February 4, 2013 and the pharmacists who filled the prescriptions, the Government argued that Respondent had not even identified these persons and that their proposed testimony was ''stated only in general terms [and] lack[ed] conclusions.'' ALJ Ex. 36, at 7 (No. 15–6); ALJ Ex. 36, at 7 (No. 15–7).

In its motion, the Government also addressed Respondents' use of a thumb drive to provide its exhibits. ALJ Ex. 36, at 3 (No. 15–6); ALJ Ex. 39, at 3 (No. 15–7). According to the Government, the thumb drive contained ''hundreds of different files, which contain, collectively, thousands of pages of documents,'' of which only one file, which ''consist[ed] of 1490 pages,'' ''appeared to be marked for identification.'' ALJ Ex. 36, at 3–4 (No. 15–6); ALJ Ex. ALJ Ex. 36, at 3–4 (No. 15–7). The Government further stated that the other files were ''neither marked for identification nor paginated.'' ALJ Ex. 36, at 4 (No. 15–6); ALJ Ex. 36, at 4 (No. 15–7). The Government argued that Respondents' submission of their proposed documentary evidence did not ''comply with the ALJ's order in terms of labeling and form.'' ALJ Ex. 36, at 8 (No. 15–6); ALJ Ex. 36, at 8 (No. 15–7). The Government also argued that because ''none of [Respondents'] summarized testimony reference[d] any particular documents or page, [it was] unable to ascertain whether any of the documents . . . would be relevant to [the] proceeding.'' ALJ Ex. 36, at 9 (No. 15–6); ALJ Ex. 36, at 9 (No. 15–7).

On January 21, 2015, each Respondent filed a Response to the Government's Motion; as with Respondents' other filings, the Responses appear to be identical. *Compare* ALJ Ex. 53 (No. 15–6) *with* Response to Government's Motion *In Limine* (No. 15–7) (hereinafter, Superior II Response to Motion *in Limine*).[7] Therein, Respondents argued that the Government's Motions were ''completely devoid of intellectual integrity'' because the Government's Prehearing Statement ''fail[ed] to specifically identify a single prescription or patient and only generally refers to areas of discussion of its witnesses,'' including the proposed testimony of its expert witness. ALJ Ex. 53, at 2 (No. 15–6); Superior II Response to Motion *in Limine,* at 2. Respondents also argued that ''[t]he Government's Prehearing Statement only identifies two patients by their initials and only one by the alleged city of residence.'' ALJ Ex. 53, at 3 (No. 15–6); Superior II Response to Motion *in Limine,* at 3.[8] Respondents thus contended that the Government provided an ''inadequate description of the testimony concerning specific patients and prescriptions,'' and that they were ''placed under extreme prejudice in [their] preparation for this expedited hearing.'' ALJ Ex. 53, at 3 (No.

[6] Respondents did, however, disclose the names of the physicians as part of their Prehearing Statements. Respondents also stated that they intended to elicit testimony from the physicians ''confirm[ing] [that] they performed adequate and appropriate physical examinations of the patients,'' as well as testimony as to ''the reasonableness and necessity of the prescriptions to control the pain or other complaints of their patients as required by the standard of care and Florida statutes.'' ALJ Ex. 9, at 4 (No. 15–6); ALJ Ex. 12, at 4 (No. 15–7).

[7] While this filing is part of the record, it was not assigned an ALJ Exhibit Number and is not included on the list of ALJ Exhibits in the Superior II matter.

[8] While this was true with respect to Superior I, the Government's Prehearing Statement in Superior II identified each of the patients whose prescriptions were at issue by their initials, and with respect to 13 of the patients, either the Prehearing Statement or the Show Cause Order identified the patient's city of residence. ALJ Ex. 1, at 2–3 (No. 15–7); ALJ Ex. 6, at 4–6 (No. 15–7).

15–6); Superior II Response to Motion *in Limine,* at 3. Respondents also disputed the Government's contention that their argument should be rejected because during a December meeting with Government Counsel, they did not ask for additional information regarding the patients' names. ALJ Ex. 53, at 3 (No. 15–6); Superior II Response to Motion *in Limine,* at 3.

Respondents further took issue with the Government's contention (with respect to both pharmacies) that only a small number of the thousands of persons listed in their Prehearing Statements were actually identified as patients. ALJ Ex. 53, at 2 (No. 15–6); Superior II Response to Motion *in Limine,* at 2. According to each Respondent, it listed all of the ''patients whose prescriptions were dispensed and doctors who generated the prescriptions [that were] filled at the pharmacy during the relevant time period,'' because at the time it filed its Prehearing Statement, the Government was ''the only party . . . to know which patients, doctors, and pharmacists are material and relevant to the allegations they chose to include in the'' Show Cause Order. ALJ Ex. 53, at 3 (No. 15–6); Superior II Response to Motion *in Limine,* at 3. Respondents thus contend that ''the potential exclusion of material and relevant witnesses as requested by the Government . . . would be arbitrary, capricious, and an abuse of discretion.'' ALJ Ex. 53, at 3–4 (No. 15–6); Superior II Response to Motion *in Limine,* at 3–4.

As for the Government's contention that Respondents had failed to disclose the proposed testimony of the patients, doctors and pharmacists with adequate specificity, Respondents argued that ''without the identification of the prescriptions and/or patients at issue (as defined by the OSC), a specific summary of each and every potentially relevant witness is impossible within the timeframe provided.'' ALJ Ex. 53, at 6 (No. 15–6); Superior II Response to Motion *in Limine,* at 6. Continuing, Respondents argued that ''[t]he witnesses will confirm their interaction with the pharmacists in resolving 'red flags' and verify the prescriptions were issued for a legitimate medical purpose in the usual course of professional practice.'' ALJ Ex. 53, at 6 (No. 15–6); Superior II Response to Motion *in Limine,* at 6. Notably, Respondents did not maintain that the pharmacists would testify that they resolved red flags.

As for the Government's attempt to bar the testimony of Mssrs. Badawi and Crowley, Respondents argued that they ''ha[d] summarized [their] testimony to the same extent that the Government summarized its proposed testimony.'' ALJ Ex. 53, at 5 (No. 15–6); Superior II Response to Motion *in Limine,* at 5. Respondents appeared to argue that they could not offer more detail as to the testimony of these witnesses because they were ''without notice of what specific facts and opinions [would] be offered in the Government's prima facie case as the Government chose to not disclose specifics.'' ALJ Ex. 53, at 6 (No. 15–6); Superior II Response to Motion *in Limine,* at 6.

As for the Government's attempt to bar their proposed documentary evidence, Respondents argued that they were ''prejudiced by the Government's inadequate Prehearing Statement which forced Respondent[s] to incorporate and include all potential documents and witnesses from the relevant time period.'' ALJ Ex. 53, at 4 (No. 15–6); Superior II Response to Motion *in Limine,* at 4. Respondents further maintained that ''[t]his prejudice would have only been exasperated [sic] by the costs associated with production of multiple sets of paper copies of the voluminous records.'' ALJ Ex. 53, at 4 (No. 15–6); Superior II Response to Motion *in Limine,* at 4. Respondents asserted that the electronic files were organized in four separate folders, and the folder which included the documents seized pursuant to the Administrative Inspection Warrant, was simply ''a mirror copy, in the exact form, of the digital files *dumped* on Respondent by the DEA at the time of service of the Order to Show Cause.'' ALJ Ex. 53, at 4 (No. 15–6); Superior II Response to Motion *in Limine,* at 4. Respondents stated that they had no way of knowing whether folder three ''represent[ed] all documents seized and/or reviewed by the Government''; they further argued that ''the Government made no attempt to label and/or organize the material provided.'' ALJ Ex. 53, at 4 (No. 15–6); Superior II Response to Motion *in Limine,* at 4.

Concluding, Respondents argued that the Government had nearly two years to review the documents and that between February 4, 2013 (the date the AIWs were served) and the dates of service of the Show Cause Orders), ''Respondent[s] had no access to these records.'' ALJ Ex. 53, at 5 (No. 15–6); Superior II Response to Motion *in Limine,* at 5. Respondents thus argued that to exclude their ''proposed testimony and exhibits, based exclusively on circumstances created by the Government, would be an extreme abuse of discretion.'' ALJ Ex. 53, at 6 (No. 15–6); Superior II Response to Motion *in Limine,* at 6.

On January 27, 2015, the ALJ conducted the initial day of the hearing during which he addressed the Government's Motions *in Limine.*[9] With respect to the proposed testimony of the more than 5,000 patients who filled their prescriptions at Respondents, the ALJ granted the Government's Motions for two reasons. First, he found that Respondents had failed to comply with his Prehearing Order because they had ''not described with sufficient detail the testimony of the proposed witnesses.'' ALJ Ex. 7, at 3 (No. 15–6/15–7) (Journal Entry and Order From Initial Day of Hearing). Second, he found that the proposed testimony of the patients ''would not constitute relevant evidence, given the nature of the charges appearing in the Orders to Show Cause, as elaborated upon by the Government's Prehearing Statements. *Id.*

As for the proposed testimony of the physicians, the ALJ found that Respondents' Pre-hearing Statement did ''not sufficiently identify the anticipated testimony of the witnesses, nor . . . make a sufficient showing that their testimony would constitute relevant evidence.'' *Id.* The ALJ further held that this ruling applied to both those physicians who filled the prescriptions before February 4, 2013, as well as after that date. *Id.* at 3–4. As to the latter category of physicians, the ALJ barred their testimony based on the additional reason that Respondents had not ''timely identif[ied] by name the proposed witnesses,'' as again required by his Prehearing Order. *Id.* at 4. And the ALJ further barred Respondents from offering the testimony of ''any pharmacists referred to but not identified in [their] prehearing statements.'' *Id.*

The ALJ also granted the Government's motion to exclude the testimony of Mssrs. Badawi and Crowley. As for Mr. Badawi, the ALJ found that Respondent had not complied with his Prehearing Order because ''[u]nlike the articulation of specific red flags provided by the Government in its description of testimony for its expert, the Respondents' Prehearing Statements do not reveal the substance of this testimony, but instead presented only a list of areas to be discussed.'' *Id.* at 5. As for Respondents' representation that Mr. Badawi would also testify about errors he identified ''in the inventory performed by the DEA,'' the ALJ found that Respondents failed to ''articulat[e]

[9] While the ALJ termed this day as the initial day of the hearing, he did not take any evidence. Tr. 1–36.

the nature of these errors'' and there was ''[in]sufficient information regarding the timeframe used by Mr. Badawi to permit a determination that the testimony would be relevant.'' *Id.*

As for Mr. Crowley's proposed testimony regarding errors in the DEA audit, the ALJ found that Respondents ''fail[ed] to articulate what those errors were.'' *Id.* And as for his proposed testimony ''regarding procedures used by the pharmacies for resolving red flags and for complying with DEA recordkeeping requirements,'' the ALJ explained that he could not ''discern from the summary of [his] testimony whether [it] concerns the practices of the pharmacies at the time of the execution of the administrative warrants, at times before then, or at the present time.'' *Id.* at 5–6. Finding that Respondents had ''failed to comply with the prehearing order[s]'' and had also ''failed to establish that [his] proposed testimony would be relevant,'' the ALJ barred Mr. Crowley's testimony. *Id.* at 6.

The ALJ also addressed the Government's contention that Respondents' documentary evidence should be excluded. In his Order, the ALJ explained that in his Prehearing Orders he had directed the parties to exchange their exhibits on or before January 12, 2015, and that the ''failure to timely do so would result in the exclusion of the documents.'' *Id.* at 4. According to the ALJ, ''[o]n both January 9 and . . . 12, a representative of Mr. Sisco's office contacted a member of my staff, inquiring whether Respondents [could] submit documents by using electronic files; . . . on both occasions my staff member advised that only hard copies and facsimiles would be accepted.'' *Id.* The ALJ explained that on January 12, he directed his staff to return the flash drives which Respondents' counsel had sent to his office, and that as of the date of the hearing, Respondents still had not filed their proposed exhibits with his office. *Id.* at 4–5. The ALJ then explained that he had ''considered the Government's report of the contents of what presumably was on'' the flash drives, as well as Respondents' explanation as set forth in their Responses to the Government's Motions, and found that good cause existed to grant the motions and bar Respondents from introducing their proposed exhibits. *Id.* at 5. The ALJ, however, provided Respondents' counsel with the opportunity to submit its proposed exhibits as a proffer, provided it did so no later than February 10, 2015, and provided his Office with an original and two copies, as well as a copy to the Government. *Id.*

Subsequently, on February 3, 2015, the Government filed a ''Notice of Objections to Respondent's Exhibits.'' ALJ Ex. 15 (Nos. 15–6 and 15–17). Therein, the Government noted that it had received eight binders of evidence totaling nearly 4,300 pages, of which five binders appeared to be related to Superior I and three binders Superior II. *Id.* at 2. While the Government contended that it was unclear whether the Respondents were offering the exhibits as a proffer or as evidence to be admitted in the proceeding, it then explained that even if the exhibits were offered as a proffer, they should not be included in the record because Respondent had not made an offer of proof as required by 21 CFR 1316.60. *Id.* The Government further noted that none of the documents were ''self-authenticating'' and many of them, which included patient medical records, ''appear to come from sources other than the Respondents.'' *Id.* at 3.

At the first day of the evidentiary phase of the hearing, the ALJ addressed the Government's objection. Tr. 54. After re-affirming his earlier ruling which barred Respondents from introducing any documentary evidence, the ALJ then turned to the Government's contention that Respondents had not complied with 21 CFR 1316.60. On the issue of whether Respondents had made an adequate offer of proof, the ALJ asked one of Respondents' counsel if he was ''correct in understanding that the Respondent[s'] Pre-hearing Statements and the premises that [he] articulated during the initial day of hearing in support of receiving these exhibits should, taken together, be regarded as containing the statement of the substance of the evidence which you would have accompany the excluded documents?'' Tr. 58. Respondents' counsel answered ''[y]es.'' *Id.* While the ALJ had also noted that ''an offer of proof shall be part of the record only if a proper foundation has been laid for its admission,'' *id.* at 57, the ALJ did not ask Respondents' counsel to lay a foundation for any of the exhibits. *Id.* at 57–69. After noting that he received only a single copy of the proffered exhibits (vice the three copies required by his Prehearing Order), the ALJ ordered Respondents to provide two additional copies of the proffered exhibits prior to 5 p.m. that day; he further advised that if the copies were not filed, he would return the proffered exhibits to Respondents. *Id.* at 69. Subsequently, Respondents filed the additional copies of the exhibits, and the exhibits were forwarded as a proffer.

The ALJ's Ruling on Respondents' Subpoena Requests

During the January 27 hearing, the ALJ also addressed each Respondent's request for subpoenas. Tr. 17–23. As explained above, each Respondent submitted requests for an extensive number of subpoenas but failed to include with its requests a certificate of service establishing that they had provided copies to the Government.

Asked by the ALJ to address its requests, Respondents' counsel asserted that ''the request for subpoenas was copied to [Government counsel] timely as to each of the subpoenas.'' *Id.* at 18. However, when asked by the ALJ if it was correct that he did not include a certificate of service, Respondents' counsel answered: ''If the Court says that that wasn't included then I'll accept that. However, I will represent that everything that I provided to the Court has been provided to'' Government counsel. *Id.* at 20. The ALJ then asked the Government's counsel if he had been provided with copies of the subpoena requests. *Id.* at 21. Government counsel answered that he had received a thumb drive which ''contains so many thousands of pages of documents'' that he ''did not look for specific subpoenas.'' *Id.* Subsequently, Respondents' counsel confirmed that he had sent the subpoena requests to the Government electronically. *Id.* at 22.

The ALJ then explained that in his Prehearing Orders, he had advised the parties that subpoena requests that did not comply with his instructions would be returned without further action; he also explained that Respondents had neither objected to nor sought clarification of the Prehearing Orders. *Id.* at 23. Finding that Respondents had not complied with his Prehearing Orders, the ALJ announced that he would be returning Respondents' subpoena requests without further action. *Id.* The ALJ did not address whether Respondents had made an adequate showing as to relevancy with respect to either the patients or the physicians. *Id.* at 17–23.

Respondents' Motions for a Daubert Hearing and To Exclude the Testimony of the Government's Expert

On January 15, 2015, Respondents also filed motions to exclude the testimony of the Government's pharmacy expert Robert Parrado. ALJ Ex. 41 (No. 15–6); ALJ Ex. 41 (No. 15–7). The basis of Respondents' motions was that ''Mr. Parrado's proposed opinions are based on nothing more than a cursory review of the written prescriptions to the exclusion of all

other information,'' and that he ''did not apply any reliable methodology as mandated'' by *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579 (1993), and its progeny. ALJ Ex. 41, at 2 (No. 15–6); ALJ Ex. 41, at 2 (No. 15–7). Respondents also argued that Mr. Parrado was ''not qualified to render any opinions regarding whether the physician issuing the prescriptions did so for a legitimate medical purpose in the usual course of professional practice.'' ALJ Ex. 41, at 2 (No. 15–6); ALJ Ex. 41, at 2 (No. 15–7) (both citing Fla. Stat. 766.102(5) (''person may not give expert testimony concerning the prevailing professional standard of care unless the person is a health care provider who holds an active and valid license and conducts a complete review of the pertinent medical records'').

Respondents argued that the ALJ was required to perform a ''gatekeeping'' function in determining whether Mr. Parrado's testimony was admissible. ALJ Ex. 41, at 2 (No. 15–6); ALJ Ex. 41, at 2 (No. 15–7). They further argued that under *Daubert,* the Government was required to show that: (1) Mr. Parrado was qualified to testify as an expert; (2) that he used a sufficiently reliable methodology in reaching his conclusions; and (3) that his testimony would assist the trier of fact. ALJ Ex. 41, at 2 (No. 15–6); ALJ Ex. 41, at 2 (No. 15–7). Respondents then suggested that under *Daubert,* the ALJ was required to consider ''whether the theory or technique'' used by Mr. Parrado ''has been subject to peer review and publication.'' ALJ Ex. 41, at 4 (No. 15–6); ALJ Ex. 41, at 4 (No. 15–7). According to Respondents, Mr. Parrado's testimony should be excluded as unreliable because ''he failed to conduct a thorough investigation and failed to base his proposed opinion on any reliable methodology.'' ALJ Ex. 41, at 5(No. 15–6); ALJ Ex. 41, at 5 (No. 15–7).

The Government opposed the motions. Quoting agency precedent, the Government argued that where, as here, non-scientific expert testimony is at issue, the expert's '' 'knowledge and experience' '' may provide a sufficient foundation for concluding that his testimony is reliable. ALJ Ex. 50, at 3 (quoting *Holiday CVS, L.L.C., d/b/a CVS Pharmacy No. 219 and 5195,* 77 FR 63316, 62334 (2012) (quoting *Surles ex rel. Johnson* v. *Greyhound Lines, Inc.,* 474 F.3d 288, 295 (6th Cir. 2007))). The Government noted that Mr. Parrado has been a licensed pharmacist for more than 40 years and had been ''the recipient of numerous professional appointments.'' *Id.* The Government further argued that at the hearing, Respondents would ''have ample opportunity to question [him] regarding his knowledge and experience, but . . . to exclude him on that basis, prior to trial, is both misguided and premature.'' ALJ Ex. 50, at 4. The Government also argued that Respondents provided no support for their contention that Mr. Parrado's testimony should be excluded because ''he did not interview [the] patients or other persons.'' ALJ Ex. 50, at 4.

The ALJ denied Respondents' motions. The ALJ reasoned that in each Show Cause Order and its Prehearing Statements, ''the Government identifie[d] red flags or other conditions which, according to the Government, triggered a corresponding obligation on the part of pharmacies who were presented with a number of prescriptions. The thrust of this evidence is [not] dependent upon scientific or technical analysis, but upon documentary or testimonial evidence establishing or rebutting the claimed corresponding obligation.'' ALJ Ex. 7, at 7 (Nos. 15–6 and 15–7).

The ALJ then held that ''[t]he Government ha[d] made a sufficient showing to permit Mr. Parrado to appear and give testimony.'' *Id.* Continuing, the ALJ explained that at the hearing, he would allow Respondents to question Mr. Parrado as to his qualifications and the methodology he used, but that he was not making a ''preclusive ruling prior to the time [he] testified.'' *Id.* The ALJ thus denied Respondents' motions to either conduct a separate hearing on the admissibility of Mr. Parrado's testimony or to exclude his testimony prior to the hearing. *Id.*

Respondents' Motions for a Continuance

On January 15, 2015, each Respondent also moved for a continuance. ALJ Ex. 42 (No. 15–6); ALJ Ex. 42 (No. 15–7). Respondents sought a continuance of the proceeding ''to commence no sooner than June 2015.'' *See, e.g.,* ALJ Ex. 42, at 5 (No. 15–6). Respondents asserted that they needed the continuance ''to interview and subpoena witnesses,'' and that they ''ha[d] timely requested the issuance of numerous subpoenas and . . . ha[d] exercised due diligence in this regard.'' *Id.* at 3. Respondents further asserted that ''[d]ue to the short time period between the issuance of the order[s] to show cause and the commencement of the hearing, and the numerous potential witnesses, [they] will undoubtedly be prejudiced by a [sic] the lack of time to adequately interview and obtain service on the necessary witnesses.'' *Id.*

Respondents argued that ''the Government has had years to prepare its case whereas [they have] only been afforded a few months.'' *Id.* at 4. Continuing, Respondents contended that the Government ''has had more than 20 months to process and analyze the seized information,'' and that ''[d]uring this time, the information was not available to Respondent.'' *Id.* at 5. While Respondents then acknowledged that ''a portion of the seized information, most notably the prescriptions, was provided to [them] in electronic format,'' they then contended that ''the sheer volume of information coupled with the unreasonably short deadlines surrounding the holiday season makes analysis of the information . . . impossible.'' *Id.*

On January 27, 2015 (during the initial day of the hearing), the ALJ denied Respondents' motions.[10] In so ruling, the ALJ relied on his previous ruling that Respondents had ''failed to timely submit their request for subpoenas.'' Tr. 30. The ALJ then explained that he could not ''reconcile'' Respondents' assertion that they needed more time to prepare with the representations made in each of their Prehearing Statements that their two proposed experts had ''reviewed the prescriptions at issue, the relevant inventory and ordering history and prepared summaries of the pharmacies' dispensing activities during 2011 and 2012.'' Tr. 31; *see also* ALJ Ex. 9, at 5–6 (No. 15–6); ALJ Ex. 12, at 5–6 (No. 15–7).[11] Finally, the ALJ explained that he had:

> consider[ed] a variety of factors, including the diligence and good faith of the parties seeking the continuance; the grounds for the delay; fairness to both parties; the need for orderly administration of justice; the length

[10] The Government did not file a response to this motion.

[11] As found above, in their Prehearing Statements, Respondents represented that Mr. Badawi would testify about ''the procedures used at Superior Pharmacy [I and II] to consider and resolve alleged 'red flags,' inventory, ordering and CSOS compliance issues. Mr. Badawi will further testify that he has reviewed the prescriptions at issue, the relevant inventory and ordering records and prepared summaries of the prescription dispensing activity at Superior Pharmacy [I and II] during 2011 and 2012, and identified significant errors in the inventory performed by the DEA.'' ALJ Ex. 9, at 6 (No. 15–6); ALJ Ex. 12, at 6 (No. 15–7).

Likewise, Respondents represented that ''Mr. Crowley will testify regarding errors in the audits performed by the agent/investigators of Superior Pharmacy [I and II]. Mr. Crowley reviewed the prescriptions, inventory and CSOS records of Superior Pharmacy [I and II]. Mr. Crowley will further testify regarding Superior Pharmacy[I and II]'s procedure for resolving potential 'red flag' issues and compliance with recordkeeping requirements related to inventory records, DEA–222 order forms and CSOS issues.'' ALJ Ex. 9, at 5 (No. 15–6); ALJ Ex. 12, at 5 (No. 15–7).

of the delay requested; whether other continuances have been requested and received; the inconvenience to litigants, witnesses, opposing counsel and the Court; and whether the requesting party contributed to the circumstances which give rise to the request for a continuance and any other relevant factors depending on the facts of the case.

Tr. 31. The ALJ then found that ''cause has not been shown to delay this hearing'' and denied the Respondents' motions. *Id.*

With the evidentiary phase of the hearing set to begin on February 10, 2015, on February 6, 2015, Respondents filed a second Motion for Continuance. ALJ Ex. 12, at 1 (No. 15–6/15–7). The basis for the motion was that on January 28, 2015, they had retained a third counsel, who previously been involved in resolving a matter involving another of Mr. Obi's pharmacies. *Id.* at 2. Citing ''the complexity of the issues in these matters,'' Respondents sought a continuance of three weeks to allow its additional counsel to prepare for the hearing. *Id.*

The same day, the Government objected. ALJ Ex. 19 (Nos. 15–6/15–7). It argued that Respondents had been aware of the allegations since October 16 and 17, 2014, and that ''neither Respondent has been without counsel since'' they were served with the Show Cause Orders, and that Superior I had previously retained an additional counsel. *Id.* at 3. The Government further asserted that it was ''both disingenuous and . . . legal gamesmanship to suggest that the eleventh hour appearance of a co-counsel for Superior II and a second co-counsel for Superior I constitute grounds for disrupting a proceeding that'' in its view had commenced on January 27, 2015. *Id.* It then argued that Respondents had not demonstrated any hardship that justified a continuance and they ''ha[d] never *timely* objected to any'' of the dates set by the ALJ, ''including the date and location of the hearing which'' had been set ''more than two months'' earlier. *Id.* at 4. Finally, the Government stated that it was prepared to put on its case and that ''all of [its] witnesses are travelling to Arlington, Virginia, and have set aside time to participate in this matter.'' *Id.* The Government thus argued that ''any further delay'' would cause it prejudice. *Id.*

The ALJ denied Respondents' motion. ALJ Ex. 24, at 2 (Nos. 15–6/15–7). As with Respondents' previous motions for a continuance, the ALJ explained that he had considered various factors and found that ''cause has not been shown to delay the hearing.'' *Id.*

The Evidentiary Hearing and ALJ Decision

On February 10 and 11, the ALJ conducted the evidentiary phase of the hearing at the DEA Hearing Facility in Arlington, Virginia. At the hearing, the Government elicited the testimony of four witnesses, including its expert witness, Mr. Robert Parrado; the Government also introduced various documents into evidence. Consistent with the ALJ's order granting the Government's Motions *in Limine,* Respondents were precluded from calling any witnesses and introducing any documentary evidence. The ALJ did, however, allow Respondent to submit ten binders of documents (totaling nearly 4,300 pages) as a proffer.

Following the hearing, both parties submitted briefs containing proposed findings of fact and conclusions of law (hereinafter, referred to as Post-Hearing Brief). On April 9, 2015, the ALJ issued his Recommended Decision (hereinafter, cited as R.D.); according to the Certificate of Service, on April 10, the ALJ's law clerk sent a copy of the Decision to all three of Respondents' counsels by Federal Express.

In the Recommended Decision, the ALJ relied on the Government's evidence with respect to factors two and four to conclude that ''the Government has established its *prima facie* case by at least a preponderance of the evidence that Respondents' continued . . . registrations would be inconsistent with the public interest.'' R.D. 87. Further finding that ''Respondents have failed to rebut that case through a demonstration of sufficient remediation,'' the ALJ recommended that I revoke each Respondent's registration and deny any pending applications to renew or modify its registration. *Id.*

On May 4, 2015, the ALJ transmitted the record to my Office. On May 6, 2015, Respondents filed a brief captioned as: Exceptions to the Recommended Decision and Request for Removal of the ALJ (hereinafter, cited as Resp.' Exceptions). Respondents, however, offered no showing of good cause to excuse the untimely filing of their brief. *See generally id.* In response, on May 7, 2015, the Government filed with my Office a motion to strike Respondents' Exceptions as untimely or, in the alternative, to respond to their Exceptions. *See* Gov. Motion to Supplement the Record, Strike Respondent[s'] Untimely Filed Exceptions to the Recommended Decision of the Administrative Law Judge Or, In the Alternative, Respond to Exceptions. Because Respondents have not demonstrated good cause to excuse the untimely filing of their Exceptions, I consider the claims raised therein only if they were previously raised in their Post-Hearing Brief.

Having carefully considered the entire record in this matter and, in particular, the claims of error raised by Respondents in their Post-hearing Brief, I do not adopt the ALJ's findings of fact and conclusions of law with respect to the allegations that each Respondent's pharmacists violated 21 CFR 1306.04(a) and 1306.05(a). I do, however, adopt the ALJ's findings of fact and legal conclusions with respect to: (1) The allegations pertaining to the audits conducted of each pharmacy, (2) the allegations that Respondents were not properly maintaining required records including their schedule II order forms, and (3) that for purchases made using the electronic Controlled Substance Order System, Superior II was not electronically linking its receipt records to its purchase records. I further find that Respondent Superior II violated DEA regulations by allowing a non-authorized person to place electronic orders using the key assigned to an authorized person. I therefore conclude that the Government has made out a *prima facie* case to support revocation of Respondents' registrations. And because Respondents have produced no evidence of any corrective measures they have undertaken, I will order that their registrations be revoked and that any pending applications be denied. As ultimate fact finder, I make the following.

Findings of Fact

The parties stipulated that Respondent Superior I holds DEA Certificate of Registration BS9255274, pursuant to which it is authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered address of 3007 W. Cypress St., Suite 1, Tampa, Florida. ALJ Ex. 7, at 2 (Nos. 15–6/15–7).

The parties stipulated that Respondent Superior II holds DEA Certificate of Registration BS9699731, pursuant to which it is authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered address of 5416 Town 'N' Country Blvd., Tampa, Florida. *Id.*

The DEA Investigation

On February 4, 2013, DEA Investigators executed Administrative Inspection Warrants at Respondents Superior I and Superior II. Tr. 370–71; 471. With respect to Superior I, the Investigators seized the original

prescriptions for its schedule II and III dispensings, as well as its schedule II order forms (DEA-Form 222), invoices, and inventory records. *Id.* at 372. At Superior I, a DEA Investigator (who assisted the lead Investigator) also conducted an inventory of the controlled substances then on hand with the assistance of the pharmacist on duty, who verified the count; the Investigator also obtained a copy of an inventory taken by Superior I which was dated May 2, 2011. *Id.* at 373–78. According to a DI, because the May 2, 2011 inventory ''did not include all the drugs that were a part of the audit,'' he asked the lead Investigator to contact the pharmacy for additional inventory records, and on February 11, 2013, Superior I provided additional records which included a ''bi-annual inventory'' and an ''in-house inventory.'' *Id.* at 378–79.

Likewise, with respect to Superior II, the lead Investigator on the warrant testified that she seized the original schedule II prescriptions and the pharmacy's purchasing records for the drugs that were subject of the audit; the DI also testified she obtained the pharmacy's schedule II order forms as well as a perpetual inventory maintained by the pharmacy which was dated July 31, 2012. *Id.* at 472, 474, 477. The DI also took an inventory of the controlled substances then on hand, with the DI witnessing Superior II's pharmacist counting of the pills. *Id.* at 477.

As part of the investigations, the Government provided various schedule II prescriptions which were dispensed by each pharmacy to its expert Mr. Robert Parrado, who reviewed them to determine if they were dispensed in compliance with the Controlled Substances Act. Mr. Parrado testified that he obtained his B.S. in Pharmacy in 1970 from the University of Florida College of Pharmacy and that he has held a Florida pharmacist's license since 1971. Tr. 122; GX 2, at 1 (No. 15–6/15–7). Mr. Parrado testified that he has practiced as a pharmacist at both community pharmacies as well as hospital pharmacies; he also testified that he had been the Pharmacy Department Manager at multiple pharmacies, including two pharmacies that he owned for approximately 19 years. Tr. 124–26; GX 2, at 1–2.

Mr. Parrado was a member of the Florida Board of Pharmacy from January 2001 through February 2009, and had served as both Vice Chairman and Chairman of the Board. Tr. 128–29; GX 2, at 3. He is a member of the Florida Pharmacy Association, having served as both its President and then Chairman of the Board. GX 2, at 3. He is also a member of the Hillsborough County Alcohol & Drug Abuse Task Force, the National Community Pharmacists Association, and the American Society for Pharmacy Law. *Id.* Finally, he has made numerous presentations on the dispensing of controlled substances by pharmacists, *id.* at 3–7, and has testified as an expert witness for both the prosecution and defense in criminal and administrative matters. Tr. 133; *see also id.* at 152 (answering ''no'' when asked on *voir dire* if, in criminal matters, he has always testified for the Government).

Asked to explain what the standard of care (in Florida) requires of a pharmacist who is presented with a prescription for a controlled substance, Mr. Parrado testified:

> You have to ensure that the prescription is appropriate and that it's valid. And in doing that he has to look at the prescription. He has to understand the nature of the drug, the nature of the disease state that they're treating, the appropriateness of the therapy and the dosing.
>
> And then make sure that the prescription was issued under . . . the valid circumstances of a physician . . . having written the prescription in the course of his practice and that the prescription is . . . for [a] legitimate medical purpose.

Id. at 137.

Asked to explain what a ''red flag'' is as it relates to the dispensing of controlled substances, Mr. Parrado then testified that:

> [a] red flag is anything that will cause the pharmacist concern as to the validity of that prescription. It could be numerous things.
>
> And a lot of times it's just dependent on the patient presenting the prescriptions or the circumstances. Or just looking at the prescription itself might raise a red flag . . . and cause you concern.

Id. at 138.

Mr. Parrado then proceeded to identify various red flags, including if the prescription was for ''a known drug of abuse'' and if the dosing is ''appropriate.'' [12] *Id.* Continuing, Mr. Parrado explained that after ''mak[ing] sure the dosing is appropriate . . . you look at the quantity of tablets'' and ask if it is ''an appropriate therapy for the condition . . . [t]hat the physician is treating.'' *Id.* at 139. Mr. Parrado then testified that he looks at what he termed the ''triangle''—the locations of ''the patient['s] home, the physician's office and the pharmacy'' and that ''whenever one of those legs seems to get a little bit long I seem to get a little concerned,'' thus leading him to ''want to verify why a person would drive a long way to [go] to a particular clinic'' and why the person would ''drive a long way from that clinic to a pharmacy.'' *Id.* at 140.

Mr. Parrado also identified other red flags to include ''[m]ultiple people presenting with identical or very similar prescriptions from the same clinic,'' as well as where a person presents prescriptions for ''cocktails that are known to be abused on the street.'' *Id.* Mr. Parrado then explained that a cocktail ''is a combination of drugs,'' which usually includes an ''opioid such as oxycodone or hydromorphone,'' ''a benzodiazepine such as Xanax or Valium,'' and ''a muscle relaxant such as Soma.'' *Id.* at 140–41.

Mr. Parrado further identified as a red flag the circumstance where multiple persons present the ''same prescriptions'' from either ''the same practitioner'' or ''clinic.'' *Id.* at 141. Mr. Parrado then explained that multiple persons getting the same prescriptions ''from the same clinic'' would be a red flag because ''there's supposed to be an individualization of therapy whenever a physician is ordering a pain medication.'' [13] *Id.* Of similar import, Mr. Parrado testified that he was familiar with the term ''pattern prescribing,'' which he explained was when ''prescriptions com[e] from the same clinic in . . . the same drug,'' with the same or ''very similar'' dosing and quantities. *Id.* at 142. Reaffirming his earlier testimony, Mr. Parrado explained while ''there could be a small difference'' in the quantity (*i.e.,* 168 vs. 180 pills) prescribed, ''[t]hat doesn't

[12] At this point, Respondents' counsel objected on the ground that the testimony was ''outside the scope of the'' Government's Prehearing Statements. Tr. 138. However, in its Prehearing Statements, the Government notified Respondents that Mr. Parrado would identify and discuss ''prescriptions for controlled substances which are known to be highly abused'' and ''prescriptions for quantities of narcotics that exceeded the recommended daily dosages.'' ALJ Ex. 6, at 3 (No. 15–6); ALJ Ex. 7, at 3 (No. 15–7). I thus find that the ALJ properly overruled the objection.

[13] Here again, Respondents objected to the testimony, asserting that it was ''outside the scope of [Mr. Parrado's] testimony'' and that Mr. Parrado was not ''qualified to testify about what the standard of care is for . . . a healthcare practitioner'' under Florida Statute § 766.102. Tr. 141–42. Of note, in its Prehearing Statements, the Government disclosed to Respondents that Mr. Parrado would discuss ''prescriptions issued to multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor.'' ALJ Ex. 6, at 3 (No. 15–6); ALJ Ex. 7, at 3 (No. 15–7). The ALJ overruled the objection. Tr. 142. Respondent did not, however, explain how it was prejudiced because the Government then asked whether a red flag was also presented because the prescriptions came from the same clinic. As for Respondent's contention that Mr. Parrado was not qualified under the Florida Statute to render an opinion on the issue, Florida law does not control the scope of permissible testimony in this proceeding.

show me that there's any attempt at individualization of therapy.'' *Id.*

Mr. Parrado then identified two more red flags. The first of these is when ''two people in the same household or [with the] same address were needing the exact same drugs.'' *Id.* at 143. While Mr. Parrado explained that this could possibly be legitimate, the ''onus of verifying that prescription has been seriously moved up a notch.'' *Id.* Mr. Parrado then testified that a red flag is also raised when prescriptions are issued to multiple persons with the same last name. *Id.*

Asked by the Government what steps a pharmacist should take upon being presented with a prescription that raises a red flag, Mr. Parrado explained:

> At that point the pharmacist—first thing he has to do, he has to verify that prescription with the prescriber. Florida law says you check with the prescriber.
>
> Not the prescriber's office, with the prescriber. And then you speak with the prescriber and get his opinion.
>
> You ask him the questions that you feel, you know, address your concerns. And then at that point I have to . . . use my professional judgment. Did I believe him or not.
>
> Because a physician who had written a script is always going to say, yes they wrote it. But I'm trying to determine if it was written for a legitimate medical purpose. So that's why I'm asking the questions I'm asking.

Id. at 144.

Continuing, the Government asked Mr. Parrado if some red flags are unresolvable, prompting objections by each Respondent that this testimony was beyond the scope of the summary of the testimony disclosed by the Government in its Prehearing Statements. *Id.* at 144–45. The ALJ overruled the objections [14] and Mr. Parrado testified:

> Well anytime that there is a red flag my job is to resolve that red flag. And at that point I'm having to use my professional judgment when I'm weighing all the different factors that are causing me concern.
>
> If I cannot resolve all these things that are bothering me, at that point that becomes unresolvable and I cannot fill that prescription.

Id. at 145–46. *See also id.* at 361 (agreeing that a pharmacist's education, experience and training inform his/her professional judgment).

The Government then asked Mr. Parrado if a retail pharmacist would document his/her resolution of a red flag ''somewhere?'' *Id.* at 146. Mr. Parrado answered: ''Absolutely. Anytime you have a concern with appropriateness of therapy, you always do what you have to do to resolve it and then you document it on the prescription.'' *Id.* Asked by the Government if the resolution of a red flag ''would be documented on the prescription itself,'' Mr. Parrado answered: ''Yes. Unless you have another form of doing that I don't know about, but the standard of practice has always been you document it on the prescription.'' *Id.*

On Respondent's *voir dire,* Mr. Parrado was asked whether ''the manner in which a pharmacist documents their [sic] efforts to resolve red flags is not mandated by any statute, regulations or guidance document?'' *Id.* at 154. Mr. Parrado answered: ''The pharmacist has a duty to verify that's done. And when he's done that he needs to document it. Because if you haven't documented it you haven't done it.'' *Id.* Upon further questioning by Respondents, Mr. Parrado acknowledged that neither the Florida Statutes nor the Florida Administrative Code state where the pharmacist has to document his/her resolution of a red flag. *Id.* at 156.

On further *voir dire* by Respondents, Mr. Parrado testified that his opinions were not based on conversations he had with the pharmacists at Respondents, or any statements of the pharmacists provided to him by DEA. *Id.* at 158. He also testified that his opinions were not based on any statements made by the patients, or the prescribers. *Id.* at 158–

[14] This was the first of several objections to the Government's elicitation of testimony from its Expert as to whether some of prescriptions presented red flags that could not be resolved. As Respondents argued, the Government Pre-hearing Statements ''do [ ] not anywhere discuss irresolvable red flags. And this is a last minute attempt to prejudice the ability of the Respondent[s] to put on a case here.'' Tr. 144.

One of the fundamental tenets of Due Process is that the Agency must provide a respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action. *See NLRB* v. *I.W.G., Inc.,* 144 F.3d 685, 688–89 (10th Cir. 1998); *Pergament United Sales, Inc., v. NLRB,* 920 F.2d 130, 134 (2d Cir. 1990). *See also* 5 U.S.C. 554(b) (''Persons entitled to notice of an agency hearing shall be timely informed of . . . the matters of fact and law asserted.'').

However, '' '[p]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law.' '' *Citizens State Bank of Marshfield* v. *FDIC,* 751 F.2d 209, 213 (8th Cir. 1984) (quoting *Aloha Airlines* v. *Civil Aeronautics Bd.,* 598 F.2d 250, 262 (D.C. Cir. 1979)). *See also Boston Carrier, Inc.* v. *ICC,* 746 F.2d 1555, 1560 (D.C. Cir. 1984) (quoted in *Edmund Chein,* 72 FR 6580, 6592 n.21 (2007) (''an agency is not required 'to give every [Respondent] a complete bill of particulars as to every allegation that [he] will confront''). Thus, the failure of the Government to disclose an allegation in the Order to Show Cause is not dispositive, and an issue can be litigated if the Government otherwise timely notifies a respondent of its intent to litigate the issue.

The Agency has thus recognized that ''the parameters of the hearing are determined by the prehearing statements.'' *Darrell Risner, D.M.D.,* 61 FR 728, 730 (1996). Accordingly, in *Risner,* the Agency held that where the Government has failed to disclose ''in its prehearing statements or indicate at any time prior to the hearing'' that an issue will be litigated, the issue cannot be the basis for a sanction. 61 FR at 730. *See also Nicholas A. Sychak, d/b/a Medicap Pharmacy,* 65 FR 75959, 75961 (2000) (noting that the function of prehearing statements is to provide Due Process through ''adequate . . . disclosure of the issues and evidence to be submitted in . . . proceedings''); *cf. John Stafford Noell,* 59 FR 47359, 47361 (1994) (holding that notice was adequate where allegations were not included in the Order to Show Cause but ''were set forth in the Government's Prehearing Statement'').

However, consistent with numerous court decisions, the Agency has also held that even where an allegation was not raised in either the show cause order or the prehearing statements, the parties may nonetheless litigate an issue by consent. *Pergament United Sales,* 920 F.2d at 135–37; *see also Duane* v. *Department of Defense,* 275 F.3d 988, 995 (10th Cir. 2002) (discussing *Facet Enterprises, Inc., v. NLRB,* 907 F.2d 963, 974 (10th Cir. 1990); ''we held that defendant had constructive notice of an alternate theory of liability not described in the formal charge when the agency detailed that theory during its opening argument and at other points during the hearing and when the defendant's conduct revealed that it understood and attempted to defend against that theory''). *See also Grider Drug #1 & Grider Drug #2,* 77 FR 44070, 44077 n.23 (2012) (holding that while the Government did not provide adequate notice of its intent to litigate an allegation in either the show cause order or its prehearing statements, where respondents ''did not object that the allegation was beyond the scope of the proceeding and that they were denied adequate notice of it'' and ''fully litigated the issue,'' the allegation was litigated by consent) (citing *Citizens State Bank,* 751 F.2d at 213; *Kuhn* v. *Civil Aeronautics Bd.,* 183 F.2d 839, 841–42 (D.C. Cir. 1950); and *Yellow Freight System, Inc.,* v. *Martin,* 954 F.2d 353, 358 (6th Cir. 1992)).

Here, I conclude that the ALJ erred when he overruled Respondents' objections to the testimony, as neither the Show Cause Orders, nor the Government's Prehearing Statements ever identified any prescription as presenting red flags that could not be resolved. As the Second Circuit has explained, ''[t]he primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior.'' *Pergament United Sales,* 920 F.2d at 135 (citation omitted). The defense of the allegation that a prescription presented red flags that could not be resolved requires entirely different proof, *i.e.,* testimony as to why a prescription did not lack a legitimate medical purpose, than the defense of the allegation that a pharmacist failed to resolve red flags, and Respondents' multiple objections make clear that they did not consent to the litigation of the issue. Accordingly, the Expert's testimony to this effect cannot be considered in determining whether

Respondents' pharmacists violated their corresponding responsibility under 21 CFR 1306.4(a).

59.[15] Over Respondents' objections,[16] Mr. Parrado was accepted as an expert. *Id.* at 165.

Mr. Parrado then testified that he was retained to ''review the prescriptions.'' *Id.* at 166. He also acknowledged having ''reviewed some patient records'' and ''a patient profile,'' before clarifying that ''the main thing [he] relied on was the prescriptions and those partial patient records.'' [17] *Id.*

The Superior I Prescriptions

The Government then proceeded to question Mr. Parrado regarding the 25 prescriptions contained in Government Exhibit 3 (No. 15–6). *Id.* at 167. Each of the prescriptions was issued by a physician at the 24th Century Medical Center, which, according to the prescriptions, was located at 7747 W. Hillsborough Avenue in Tampa. GX 3. Sixteen of the prescriptions were issued on August 5, 2011 for oxycodone 30 and were filled by Superior I on the same day. *See id.* at 1–16; Tr. 169. Moreover, 13 of these 16 prescriptions were written by the same physician (Dr. C.), with the remaining three written by another physician (Dr. R.). GX 3, at 1–16.

Each page of this exhibit contains two images; one showing the front of the prescriptions; the other showing the back. *See generally* GX 3. With respect to the first page of the exhibit, Mr. Parrado testified that the bottom image was the back of the prescription. Tr. 169. He explained that when a pharmacy fills a prescription, its computer generates labels, one of which goes on the prescription bottle and the other goes on the prescription. *Id.* Mr. Parrado then explained that the number following the letters ''RX'' on the label was the prescription number and that the number is generated sequentially by the pharmacy's ''computer as prescriptions are being filled.'' *Id.* at 170–71. However, Mr. Parrado subsequently testified that ''[d]epending on the computer format they have, some will generate a number with the first number being different . . . depending on the schedule of the drug.'' *Id.* at 174.

The Government then asked Mr. Parrado whether there were ''any red flags associated with'' the 16 prescriptions, which were filled on August 5, 2011. *Id.* at 178. Mr. Parrado testified that the prescriptions presented multiple red flags:

> Well first thing I would see was the drug, [o]xycodone, 30 milligrams. Then I would see that they're all coming from the same clinic. They're all for the same strength written by the same physician on the same day.
>
> So there's multiple patients coming from the same clinic. Which was one of my concerns earlier. Multiple people presenting from the same clinic with a like or similar prescription.
>
> These are definitely alike in similar prescriptions. So that would be my first red flag.
>
> Then the next red flag I would have looked at was the dosing. The appropriateness of therapy. A red flag I would have to resolve at this point was knowing that 80 milligrams a day of [o]xycodone is a lethal dose to an opioid naïve patient. These are much higher than 80 milligrams a day dosing.
>
> I would have to verify—I'd have to feel good about the fact that the patient had been on this drug therapy and established to this dose. Would have been the first thing.
>
> Then the next thing I would have looked at would have been the patient[']s address. How far he drove to get there.
>
> Then another thing I would have looked at was what . . . did he pay for it with cash. And how much did he pay. How much is he willing to pay for.[18]

Id. at 178–79.

Mr. Parrado further testified that each of the 16 prescriptions was paid for in cash. *Id.* at 181. Asked whether based on his experience and knowledge of retail pharmacy practice, the prices being charged by Respondent for these prescriptions ''were considered high prices for oxycodone,'' Mr. Parrado answered ''[v]ery.'' *Id.* at 182. Mr. Parrado subsequently explained that ''these prices are very, very high'' and that this would be an additional red flag. *Id.*at 183. As the evidence shows, 13 of the patients paid $784 or more for their prescriptions, and five of the patients paid $952 or more. GX 3, at 1–16.

The Government then questioned Mr. Parrado regarding the red flags presented by the relative location of the patients to the prescriber and Superior I. With respect to the prescriptions reproduced at pages one (112 oxycodone 30 to M.L.) and nine (224 oxycodone 30 to V.P.), both patients' addresses were listed as being in Spring Hill, Florida.[19] *See id.* at 1, 9. According to Mr. Parrado, Spring Hill is located 45 to 50 miles from Superior I.[20] Tr. 185. Mr. Parrado then explained that ''[t]here

[15] Regarding whether his opinions were based on the presentations on red flags made by the former head of the Agency's Office of Diversion Control, Mr. Parrado acknowledged that he has seen these presentations on two occasions. Tr. 159. However, Mr. Parrado stated that the presentations ''reinforced'' his existing opinions on red flags. *Id.* at 160. As for the presentations he had previously given, Mr. Parrado acknowledged that he no longer considers a patient's asking for a drug by brand name to be a red flag. *Id.* at 161–62.

When asked whether his opinions were based on information in the DEA *Pharmacist's Manual,* Mr. Parrado answered ''yes'', and when asked if he disagreed with anything in the *Manual* as it relates to red flags and their resolution, answered ''no.'' *Id.* at 163.

[16] The basis of Respondents' objection to Mr. Parrado being accepted as an expert was that he ''is a practicing pharmacist. He's experienced in retail pharmacy but qualification as an expert, there's no need.'' Tr. 165. Given Mr. Parrado's extensive years of practice as a retail pharmacist; his years as a member of the Florida Board of Pharmacy, which includes service as both Vice Chairman and Chairman; his involvement in the Florida Pharmacy Association which includes his service in leadership positions; his membership in other professional associations; and his numerous presentations; the ALJ properly overruled Respondents' objection.

[17] On cross-examination, Mr. Parrado testified that he had review only one patient profile ''a couple of weeks'' before the hearing. Tr. 232.

[18] At this point, Mr. Parrado testified that ''in that time period,'' oxycodone cost from $.33 to $1.00 per tablet, at which point Respondents' counsel objected to the testimony, asserting that it was outside the scope of the Government's Prehearing Statements and that there was no foundation for Mr. Parrado's testimony. Tr. 179. While the Government's Prehearing Statement did not disclose the precise prices he testified to, the Government did disclose that Mr. Parrado would ''identify and discuss . . . prescriptions for individuals playing [sic] high prices . . . for controlled substances with cash.'' ALJ Ex. 6, at 3 (No. 15–6). Moreover, the label attached to the back of each of the prescriptions contains data as to both the price to the patient and the cost of the prescription and the prescriptions were provided to Respondents prior to the hearing. The labels suggest that Mr. Parrado's testimony as to the cost per tablet was accurate. *See, e.g., generally* GX 3 (No. 15–6).

As to the issue of foundation, Mr. Parrado testified that ''I know the pharmacy I was working in at that time [was] paying about $.33 a pill for [o]xycodone.'' Tr. 182. He then added that the average price charged to a patient ''may have gotten to a $1.00.'' *Id.* On cross-examination, Mr. Parrado further testified that his knowledge of pricing was not based on his having called individual pharmacies, but rather his ''general knowledge of what the market place was.'' Tr. 242.

[19] *See also* GX 3, at 2 (Rx for 160 oxycodone 30 to J.R.).

[20] Here again, Respondents objected to Mr. Parrado's testimony, arguing that the Government's Prehearing Statement did not disclose that he was ''going to be offering testimony with regard to the distances between locations or the relative locations of these patients and the pharmacy.'' Tr. 184. Respondents further argued that they had ''prepared to cross examine the person who [the Government] said would testify to that. It was the intelligence analyst. It is not Mr. Parrado.'' *Id.*

It is correct that the Government did not disclose in its Prehearing Statement for Superior I that Mr. Parrado would specifically testify about the distances between Superior I and the towns of Spring Hill (as well as New Port Richey and others). It also true that in its Prehearing Statement, the Government indicated that it intended to call a different witness (an intelligence analyst) to testify about a chart she created showing the large number of Superior I's patients who lived long distances from the pharmacy. However, the Government also disclosed that it intended to ask the ALJ to take official notice of the approximate mileage between Superior I and the various municipalities where the patients lived. Moreover, the distances between Superior I and the towns of Spring Hill and New Port Richey are disputable only to the extent one argues over the precise addresses used to ascertain that distance or the route taken. I thus conclude that Respondent cannot show how it was prejudiced by the ALJ's overruling of its objection.

are many pharmacies between Spring Hill and Tampa.'' *Id.*

Regarding the prescriptions reproduced at page four (168 oxycodone 30 S.M.) and 16 (224 oxycodone 30 for S.A.), Mr. Parrado testified that both patients gave addresses in New Port Richey. *Id.* He then testified that New Port Richey is ''[a]bout 40 miles north of Tampa.'' *Id.* Mr. Parrado then noted that patient addresses for other prescriptions included Bradenton (40–45 miles south and west of Tampa), *id.* at 186; Port Richey (which is next to New Port Richey), *id.* at 187; Ocala (90–100 miles north of Tampa), *id.* at 188; Gainesville (130 miles north of Tampa), *id.;* High Springs (''probably a 150 miles'' from Tampa), *id.* at 188–89; Jacksonville (200 miles north and east of Tampa), *id.* at 189–90; Alachua (140–150 miles from Tampa); *id.* at 190; Middleburg (''[c]lose to Jacksonville'' and ''about 200 miles'' from Tampa); *id.* at 191; and Uvalda, Georgia (''probably . . . close to 300 miles'' from Tampa). *Id.* at 192.

Next, the Mr. Parrado testified that each of the 16 prescriptions was ''facially invalid'' because the prescribing physician did not include the patient's address. *Id.* Mr. Parrado explained that under Florida law ''at the time [21] . . . the patient name and address had to be on the front of the prescription.'' *Id.* While Mr. Parrado testified that a missing address is a red flag, he acknowledged that the pharmacist could resolve it by adding in the patient's address. *Id.* Asked by the Government whether it appeared that Superior I's pharmacists had resolved this red flag with respect to the prescriptions reproduced at pages one and four of GX 3, Mr. Parrado acknowledged that it appeared that they had done so as evidenced by the ''computer generated sticker[s] that the pharmacist[s] put'' on the prescriptions. *Id.* at 193. However, Mr. Parrado then explained that it ''would have been [the pharmacist's] duty'' to verify that the address on the sticker ''was accurate.'' *Id.*

The Government then asked Mr. Parrado about the prescriptions found at pages 11 (RX#452161), 12 (RX#452160), 14 (RX#452156), 15 (RX#452155), and 16 (RX#452159). Tr. 194–95. Of note, these prescriptions were issued to patients who reported their addresses respectively as being in High Springs, Alachua, Middleburg, Florida; Uvalda, Georgia; and New Port Richey, Florida. *See* GX 3, at 11–12, 14–16. Specifically, the Government asked whether ''the fact that these numbers are so close together, looking at these prescriptions collectively, does that raise any additional red flags for you?'' Tr. 195. After the ALJ overruled Respondent's objection that the testimony was outside the scope of the Prehearing Statement, Mr. Parrado answered:

> Yes. Yes, it would have caught my attention that we had people coming from long distances and places that were close together, coming to get these prescriptions.
>
> What I don't see on there is, you know, it looks like the [patient address] sticker was put on the front to resolve the red flag. It doesn't tell me how they resolved the red flag.

Id.

The Government then asked Mr. Parrado about the prescriptions reproduced at pages 13 (RX#452157) and 14 (RX#452156); these prescriptions listed the patient's addresses as being in Jacksonville (J.M.) and Middleburg, Florida (B.M.). *Id.* at 196; GX 3, at 13–14. According to Mr. Parrado, these ''two prescriptions were filled sequentially for people from Middleburg and Jacksonville, which are both very close to each other.'' Tr. 196. Continuing, Mr. Parrado opined: ''So they could have travelled together to come there.'' [22] *Id.* Mr. Parrado further observed that these patients had the same last name. *Id.* at 197.

Next, the Government asked Mr. Parrado about the prescriptions reproduced at pages 14 and 15. Of note, the latter prescription was issued to a patient (C.M.), who provided an address in Uvalda, Georgia and who has the same last name as that of the patients discussed in the preceding paragraph. *See* GX 3, at 15. Mr. Parrado again opined that he believed these persons travelled together to obtain the prescriptions. Tr. 198. Asked by the Government—over the overruled objection of Respondent—whether the red flags presented by these were resolvable, Mr. Parrado explained:

> These are the kinds of prescriptions that would cause me not to be able to resolve that—this many red flags together. The long distance, the same name, the like, similar drugs, thousands of dollars involved here, in cash, would cause me . . . concern.
>
> It's not, in my practice, it's not been—the average customer doesn't come into the pharmacy with $1,000 in their pocket. You know, it's average you tell the person they have a $20 copay they get upset.
>
> For these process [sic] to be charged, you know, it's just—that's a red flag that I would have a hard time resolving.[23]

Id. at 199. Asked the same question with respect to the prescriptions reproduced at pages 13 and 14, Mr. Parrado testified: ''It would be the same answer. It's the same situation.'' [24] *Id.* at 200.

The Government then asked Mr. Parrado whether, with respect to the 16 oxycodone 30 prescriptions (GX 3, at 1–16), which were issued and filled on August 5, 2011, there was any evidence, other than the placement of the address stickers, that the red flags they presented ''were resolved?'' Tr. 200. Mr. Parrado testified: ''[t]here is no documentation to that effect on any of these prescriptions.'' *Id.* Following up, the Government asked Mr. Parrado if he had seen any evidence ''that any of the red flags [other than the missing addresses] were even investigated?'' *Id.* at 201. Mr. Parrado replied:

> In some of the partial medical records I looked at, there wasn't any evidence of any conversations between the clinics and the

[21] While Mr. Parrado referred to Florida law ''at the time,'' Florida law still requires that the face of a controlled substance prescription contain ''[t]he full name and address of the person for whom . . . the controlled substance is dispensed.'' Fla. Sta. § 893.04(c)(1)(2015).

[22] Here again, Respondent objected to the testimony as ''rank speculation'' for which there was ''no foundation.'' Tr. 196. He also argued that it was beyond scope of the Government's Prehearing Statement. *Id.* The ALJ overruled the objection.

As for Respondent's objection on the ground that the testimony was ''rank speculation,'' given that Mr. Parrado testified and the prescriptions show that: (1) These two patients had the same last name, (2) provided addresses which suggested that they lived near each other, and (3) their prescriptions bore sequential prescription numbers, Mr. Parrado's testimony was a permissible inference. In any event, even if the patients did not travel together, each of these prescriptions presented red flags.

Moreover, even acknowledging that the Government did not disclose that Mr. Parrado would testify that these two persons could have travelled to Superior together, the Government nonetheless disclosed that it intended to elicit testimony regarding Respondent's filling of multiple prescriptions for patients who travelled long distances to obtain their prescriptions. ALJ Ex. 1, at 2–3 (No. 15–6); ALJ Ex 7, at 3–5 (No. 15–6). *See also supra* note 12 (collecting cases).

[23] Here too, Respondent objected that Mr. Parrado ''ha[d] no idea what people who come into a pharmacy have in their pocket or they don't.'' Tr. 199–200. Respondent thus contended that Mr. Parrado's testimony was speculation and was outside the scope of the Prehearing Statement. *Id.* at 200. The ALJ stated that he noted the objection and that he did not need Respondent to tell him ''what should be or should not be allowed in this hearing.'' *Id.* The ALJ then explained that he had made his ruling and instructed the Government to ask its next question. *Id.*

I agree with Respondent that this testimony was speculative because the patients could well have paid for their prescriptions with credit cards. However, the prescriptions list their respective prices as $833 (RX 452157), $952 (RX452156), and $833 (RX452155). GX3, at 13–15. Regardless of the method of payment used to purchase them, Mr. Parrado testified that the cost of the prescriptions was also a red flag.

[24] This prompted the same objection by Respondent and the same ruling. Tr. 200.

pharmacist.[25] Also, this is one of the things I got out of the partial medical records, that there wasn't any evidence that they had even talked with the pharmacy. And there was nothing here being documented either.

Id.

Mr. Parrado then opined that it ''would be outside the standard of care for a pharmacist to fill these without having resolved the red flags before dispensing.'' *Id.* Asked to opine on whether, based on the prescriptions and records he reviewed, the pharmacists ''exercise[d] their corresponding responsibility to ensure that a prescription for a controlled substance was issued for [a] legitimate medical purpose,'' Mr. Parrado answered: ''[n]ot that I can tell from the records shown to me.'' *Id.* at 201–02.

The Government then questioned Mr. Parrado about the remaining prescriptions in its Exhibit 3. These included a prescription for 240 oxycodone 30 issued on December 10, 2011 to J.M.; as with the other prescriptions, the prescriber had not written the patient's address on the prescription but the prescription contained a small sticker listing J.M.'s address as Lenoir, Tennessee. GX 3, at 22 (No. 15–6). Asked if the prescription raised any red flags, Mr. Parrado noted J.M.'s address and explained that his ''first concern'' was the ''person coming from Tennessee.'' Tr. 202. Mr. Parrado identified additional red flags presented by the prescriptions, including the physician's failure to include the patient address on the prescription, that the quantity of 240 pills was a ''very high dose'' for oxycodone 30, that the prescription came ''from the same clinic,'' and that it cost $1,155. *Id.* Mr. Parrado then explained that ''[t]hose are all red flags that I could not have resolved.'' *Id.*

However, when asked by the Government if he could tell who filled the prescription, Mr. Parrado testified that the prescription bore the initials ''CD,'' thus indicating ''the pharmacist responsible'' for the script; he then added that ''there's a scribble on the front from somebody that canceled the prescription.'' *Id.* at 203. Moreover, the prescription has two diagonal lines drawn through it, along with a circle with the letter ''C'' in bold, and while there is a copy of the dispensing label attached to the back, *see* GX 3, at 22, the Government offered no further evidence to clarify whether the prescription was actually dispensed.

[25] On cross-examination, Mr. Parrado testified that he had been given the partial medical records after the New Year's holiday. Tr. 357–58.

Next, the Government asked Mr. Parrado whether the prescriptions (reproduced at GX 3, at 17–18), which are dated August 6, 2011 and bear sequential prescription numbers presented any red flags. Both of these prescriptions were issued by Dr. S.A.H., a physician at the same 24th Century Medical Center in Tampa, to two persons (E.P. and R.B.) for 150 and 140 tablets respectively of oxycodone 30. GX 3, at 17–18. Here too, the front of each prescription lacked the patient's address. *See id.* However, each prescription bore a sticker listing the patient's address, and the stickers indicated that E.P. and R.B. lived at the same street address in Milton, Florida. *See id.*

Asked by the Government whether the prescriptions presented any red flags, Mr. Parrado identified the patients' addresses and added that ''Milton, Florida is way in the [w]estern panhandle of Florida. It's well over 400 miles'' to the pharmacy. Tr. 204.[26] Mr. Parrado noted that ''both of them seem to have the same address.'' *Id.* However, he then testified that the driver's license that was in R.B.'s ''partial medical records'' listed his address as being in a different city (Pace, Florida) than Milton. *Id.* at 205. Mr. Parrado explained that the disparity between the address on the prescription and the address on the driver's license ''caused me concern that they weren't looking very closely.'' *Id.* at 205–06.

After noting that E.P.'s prescription cost $562 and R.B.'s prescription cost $525, Mr. Parrado testified that ''two people from one address paying over $1,000 would be a red flag from somebody coming . . . from 400 miles away.'' *Id.* at 206. He further noted that both prescriptions were written by the same physician and were for the same drug and in essentially the same quantities. *Id.* Mr. Parrado then testified that he had seen ''no documentation anywhere'' that Superior I's pharmacist resolved the red flags, including in the ''partial medical records,'' which contained ''no evidence that there was any conversation between the pharmacy and the physician['s] office.'' *Id.* at 206–07.

Next, the Government asked Mr. Parrado about a prescription issued by Dr. V.S. (also of the 24th Century Medical Center) and dispensed on December 2, 2011 to B.W., for 200 tablets of Dilaudid (hydromorphone) 8 mg. *See* GX 3, at 21; Tr. 207. Here again, the prescription lacked the handwritten patient's address but contained a sticker which listed B.W.'s address as being in Fort Ogden, Florida. GX 3, at 21.

Asked if the prescription presented any red flags, Mr. Parrado testified that there were multiple red flags, including that ''it's a very, very potent drug'' and that the quantity was for 200 pills. Tr. 208. Continuing, Mr. Parrado testified that:

> I have never seen a prescription in my 41 years as a pharmacist for a quantity like that of . . . Dilaudid 8 milligrams as being dosed at every . . . three to four hours.
>
> Which would be six to eight times a day. So 48 to 72 milligrams . . . would be the daily dose for a drug that the recommended upper dose be probably 24 milligrams.
>
> So it's a much higher dose then [sic] what I have ever seen as a pharmacist. And that would have caused me serious concern that I had to resolve before I could do anything, period.
>
> The fact that they came a long way, again, from Fort Ogden, from that same clinic that I'm seeing all these prescriptions from, would cause me not to be able to resolve that red flag.

Id. at 208–09.

Mr. Parrado was then asked whether a prescription (GX 3, at 19) for 196 Dilaudid 8 mg issued by Dr. P.C. and dispensed on December 1, 2011 to R.L. (Largo, Fl.) also presented red flags. Tr. 209. Mr. Parrado testified that the quantity and dosing raised the ''exact same concern'' as the dosing was ''well outside the recommended upper dosage of that drug.'' *Id.* Continuing, he explained: ''And I don't see anything where that was resolved to establish that the patient had developed a tolerance to that drug to avoid the respiratory depression that would have been inherent at that dose.'' *Id.*

Asked whether R.L.'s address in Largo was also a red flag (here too, the patient's address had not been written on the prescription but had been added by a sticker), Mr. Parrado testified that the distance was 20 to 25 miles. *Id.* at 209–10. While he acknowledged that this was not ''a very long distance,'' he

[26] Respondent's counsel objected that the testimony was outside the scope of the Government's Prehearing Statement and was rank speculation. Tr. 204–5. The ALJ overruled the objection. *Id.* at 205. Here again, the Show Cause Order specifically alleged that ''[o]n August 6, 2011, one or more Superior I pharmacists dispensed large and substantially similar quantities of thirty milligram tablets of oxycodone to two customers, E.P. and R.B., both of whom resided at the same address in Milton, Florida, which is located approximately four hundred and forty nine miles (449) from Superior I's location.'' ALJ Ex. 1, at 2 (No. 15–6). While this alone provided adequate notice, the Government's Prehearing Statement further advised that ''Mr. Parrado will further testify that, on August 6, 2011, Respondent dispensed large quantities of thirty milligram oxycodone to two individuals, E.P. and R.B., who resided at the same address in a city located more than 440 miles . . . from Respondent's pharmacy.'' ALJ EX. 7, at 4 (No. 15–6). The ALJ thus properly overruled the objection.

explained that ''the fact that there's so many coming from outside the area just starts compounding the fact that this is almost . . . like a destination clinic or destination pharmacy where people know to go there.'' *Id.* at 210. Mr. Parrado then testified that he found no evidence that Superior I's pharmacist attempted to resolve the red flags.

As for the prescription (GX 3, at 20), which was issued by Dr. R. (also of 24th Century) to C.L. for 224 Dilaudid 8 mg on December 1, 2011 and filled the same day, Mr. Parrado again found the quantity to be a red flag, testifying that this would be ''a lethal dose to an opioid naïve patient.'' Tr. 211. He then explained that ''there's nothing here to show that the patient has developed a tolerance to this drug.'' *Id.*[27] As for the prescription (GX 3, at 23), which was issued by Dr. V.S. (of the same clinic) to M.A. for 224 Dilaudid 8 mg on December 2, 2011 and filled the same day, Mr. Parrado testified that the ''very high dose'' was a red flag and that there was no evidence that the patient had developed tolerance to the drug. Tr. 212.

Concluding its direct examination of Mr. Parrado regarding the Superior I prescriptions, the Government asked if he had an opinion as to whether the pharmacists who dispensed the prescriptions knew or had reason to know that they were issued without a valid doctor-patient relationship. Tr. 220–21. After the ALJ overruled Respondent's objection,[28] Mr. Parrado explained:

> There's no documentation that I saw that there was any conversation with a physician determining that. Because at these doses there would had to have been conversation determining tolerance. There would have been conversation determining medical need at this dosing.
>
> So at that point I would have had a question in my mind, as a pharmacist filling or being presented with this prescription, that there may have been . . . not a very good valid patient–doctor relationship going on at that point in time.

Id. at 221–22.

On cross-examination, Mr. Parrado acknowledged that he could not offer an opinion as to whether any of the patients, whose prescriptions were provided in GX 3, were opioid naïve. Tr. 235–36. Asked whether it was true that he had no knowledge as to the procedures used at Superior I to revolve red flags, Mr. Parrado answered that ''[n]othing that was documented on the prescriptions showed that anything had been done.'' *Id.* at 237. After acknowledging that ''there's nothing that mandates where [documentation] has to be,'' he also acknowledged that if the resolution of the red flags was documented someplace other than on the prescription itself, the documentation wasn't provided to him, and thus he does not know whether it exists or not. *Id.* at 237–38.

While Mr. Parrado testified that he knew one of the pharmacists who worked at Superior I, he stated that he had not spoken with her about any of the prescriptions. *Id.* at 246. Nor has he discussed with any of Superior I's pharmacists the policies or procedures the pharmacy had in place from January 1, 2011 through February 4, 2013, or currently has in place, for identifying diversion and for documenting the resolution of red flags. *Id.* at 246–47.

Mr. Parrado further testified that he asked DEA ''for complete profiles on all these patients'' but was told to look at only the prescriptions. *Id.* at 247. He then testified that he believed the Agency had the profiles because he had seen some of them in the DEA's office. *Id.*

Mr. Parrado testified that he had not consulted with any other pharmacists in forming his opinions. *Id.* at 248. He also testified that he did not speak with any of the prescribers of the 25 prescriptions or with the patients who received them. *Id.* at 249. He then testified that he did not know what training or experience the prescribers had. *Id.* at 250.

Asked by Respondent whether, based on the materials provided to him by DEA, he knew if Superior I's pharmacists had called the prescribers ''to discuss any issues related to the patients or the prescriptions,'' Mr. Parrado answered that ''did not see anything to that effect.'' *Id.* at 251. He then testified that if ''[i]t wasn't documented[,] [i]n my mind, they didn't do it.'' *Id.* However, Mr. Parrado acknowledged that he did not know if this was documented other than on the prescriptions. *Id.* at 252.

Mr. Parrado did not know whether Superior I kept a paper file which included medical records on their patients. *Id.* at 254. He also did not know if Superior I's pharmacists obtained copies of MRIs, X-Rays and CT scans. *Id.* He then testified that:

> In the partial patient records that I did receive, there was evidence of some MRIs. What struck me was that these MRIs were old and not ordered by the physician who was writing these prescriptions, which would have been a red flag to me. Some of these MRIs were two/three years old. They were ordered by someone else.
>
> There were some . . . MRIs, reports didn't even have a referring prescription on it. That would have concerned me as a pharmacist filling that prescription.

Id. at 254–55.

Respondent then asked Mr. Parrado if, based on the information provided to him, he was ''aware that the pharmacists were obtaining copies of radiographic studies [and] reports of radiographic studies?'' *Id.* at 255. Mr. Parrado answered:

> No, I didn't say I saw it in the pharmacy records. I saw it in the medical records. If the pharmacist would have had access to that, that would have presented another red flag in the fact that that was an old record ordered by someone else. That would have raised the bar there if you will.

Id. Mr. Parrado then explained that he did not know the source of the medical records.[29] *Id.*

[27] In response to the Government's question whether the fact that these two prescriptions were presented the same day raised ''[a]ny additional red flags,'' Mr. Parrado testified that ''[t]hat's another pattern prescribing red flag. To me.'' Tr. 211–12. I conclude, however, that two prescriptions do not establish pattern prescribing.

[28] Respondent objected on the ground that ''[t]here's no opinion summarized anywhere in the Government's [P]re-hearing [S]tatement . . . that relates to whether or not . . . the pharmacist knew or should have known that those prescriptions were issued. And it's outside his area of expertise. It's nothing but rank speculation.'' Tr. 221.

Even assuming that the first ground for objection was that the Government did not provide notice that it intended to ask whether the pharmacists knew or should have known that the prescriptions were issued without a valid doctor-patient relationship, in its Prehearing Statement, the Government advised that Mr. Parrado ''will testify that, based on his expertise, training, and experience, and based on his review of the evidence summarized above, Respondent's pharmacists failed to exercise their corresponding responsibility to ensure that prescriptions for controlled substances were issued for a legitimate medical purpose in the usual course of professional practice.'' ALJ Ex. 7, at 5. Asking whether the prescriptions ''were issued without a valid-doctor patient relationship'' is just another way of asking whether the prescriptions ''were issued for a legitimate medical purpose in the usual course of professional practice,'' as a physician must establish and maintain a valid doctor-patient relationship to act in the usual course of practice and to issue a prescription for a legitimate medical purpose.

Nor was it beyond Mr. Parrado's expertise to opine on whether the prescriptions were issued outside of a valid doctor-patient relationship. *See United States* v. *Hayes,* 595 F.2d 258, 261 & n.6 (5th Cir. 1979) (''[A] pharmacist can know that prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science.''). Indeed, pharmacists are expected to review the patient record and each prescription for therapeutic appropriateness and identify, *inter alia,* over-utilization, incorrect drug dosage, and clinical abuse/misuse. Fla. Admin Code r.64B16–27.810(1). A pharmacist is obviously required to be able to determine when a prescription calls for the dispensing of such potent narcotics as oxycodone or Dilaudid in quantities that far exceed recommended upper dosages and would be lethal in an opioid naïve patient, let alone when a patient presents such other red flags of abuse or diversion, such as travelling long distances to obtain narcotics.

[29] Subsequently, the lead Investigator testified that the medical records had been obtained

Continued

Mr. Parrado acknowledged patients become dependent and develop tolerance to opioid analgesics and that there is no upper limit as to the quantity or dose that can be prescribed. *Id.* at 260. He also acknowledged that he did not know if any of the patients who received the prescriptions in GX 3 worked in Tampa. *Id.* He also conceded that the patients ''were seeing the physicians regularly over a good period of time.'' *Id.*

Continuing, Mr. Parrado acknowledged that there is an expressway which runs from Spring Hill to Tampa, and that people may commute from the former to the latter for work. *Id.* at 261. Mr. Parrado testified that this red flag would have been resolvable if the question had been asked and answered. *Id.* at 262.

Next, Mr. Parrado testified that a pharmacist can add an address to a prescription if ''you've checked with the physician and gotten the correct thing and that matches what the patient is telling you.'' *Id.* at 263. He then acknowledged that he did not attempt to determine if any of the prescriptions in GX 3 were necessary for the treatment of chronic or recurring disease. *Id.* at 264.

On re-direct, Mr. Parrado was asked whether the one patient profile he was provided with was for P.D. (GX 3, at 24) and whether the profile showed that there was a gap in care. Tr. 268. Asked to describe what was on the document, Mr. Parrado testified that:

> [t]there was a list of dates for Mr. P.D. that showed the dates he had prescriptions filled for this drug and there was a gap of two months in there which, as a pharmacist, anybody that stops taking opioids or if I don't know he's continued taking opioids, at that point I can't fill a further prescription till I've established that.
>
> He could have been in jail. He could have been in a rehab unit. It is well-documented that patients that have gone into these things, gone back in the community and accessed a prescription at the old dosage they were on would kill them and it has killed them.

Id. at 269–70.[30] Asked by the Government whether when he reviewed this document, he saw any indication that red flags had been resolved or explained, Mr. Parrado answered ''no.'' *Id.* at 271.

Questioned by the ALJ as to where he would document the red flags presented by a prescription, Mr. Parrado testified that: ''I would have identified the red flags that concerned me when the prescription was presented. I would have noted that on the back and I would have noted what I did to resolve each one of those if there was more than one.'' *Id.* at 273. Mr. Parrado added that ''you scribble on the back and/or you write on a piece of paper and staple it to that prescription.'' *Id.*

The ALJ then asked Mr. Parrado if, in his ''experience working with other pharmacists, . . . they have other ways of making records . . . to keep track of the red flags and how they've been resolved?'' *Id.* at 274. Mr. Parrado answered: ''[n]ot in the 43 years I've been a pharmacist.'' *Id.*

On further re-cross, Respondent asked Mr. Parrado: ''Not all pharmacists document in the same way that you do, do they?'' *Id.* Mr. Parrado answered: ''[a]s a Board of Pharmacy member, I would have expected them when they came before the Board to show me that documentation. It was always on the prescription. It's always on that prescription record somehow.'' *Id.* Noting that Mr. Parrado had not been on the Board of Pharmacy for some time, Respondent then asked if he had ''ever seen in your 43 years[,] pharmacists document the same information in different ways?'' *Id.* at 275. Mr. Parrado answered: ''I've seen them document in different ways but always on the prescription.'' *Id.*

The Superior II Prescriptions

With respect to the Superior II prescriptions, Mr. Parrado testified that he reviewed them in the same manner as he did the Superior I prescriptions. *Id.* at 277. He then proceeded to identify various red flags presented by the prescriptions.

The first of these was a prescription issued by Dr. H.V.D. (also of the 24th Century Medical Center) to J.T. of Fort Meyers, Florida, for 280 oxycodone 30. GX 3, at 1–2 (No. 15–7). Here again, the patient's address was left blank and the address was provided by a sticker, which was affixed to the front of the prescription. *Id.* at 1. Mr. Parrado testified that prescription presented the following red flags: The drug having ''a high potential for abuse''; the ''very large quantity'' and ''the dosing at a very high rate, well above . . . 80 milligrams a day''; the ''patient travelling from Fort Meyers, which is . . . 150 miles or so from Tampa''; and the patient paying $1,260 cash for the drugs. Tr. 277–78.[31] Mr. Parrado then testified ''there was nothing on the prescription to show me that these things had been discussed.'' *Id.* at 279.

The second prescription was issued on December 2, 2011 by Dr. R. (the same Dr. R. of 24th Century), to R.B. of Milton, Florida (the same R.B. discussed in the Superior I findings) for 168 oxycodone 30. GX 3, at 3–4 (No. 15–7). Here again, the patient's address was left blank and the address was provided by a sticker, which was affixed to the front of the prescription. *Id.* at 3. After Mr. Parrado identified R.B. as being one the persons who filled a prescription at Superior I which presented red flags, the Government asked him to also look at the prescriptions reproduced at pages 5–6 of the exhibit. The latter prescription was also issued on December 2, 2011 by Dr. V.S. (also of 24th Century) to E.P., who again used R.B.'s address as her address; the prescription was also for 168 oxycodone 30. *Id.* at 5–6. Of further note, R.B.'s and E.P.'s prescriptions had sequential RX numbers. *Id.*

Asked if these prescriptions presented any red flags, Mr. Parrado testified that ''[t]hese were the same two patients that had gotten prescriptions filled at the other pharmacy, both with the same Milton, Florida address, both paying $924 in cash, travelling a long way, very high dosing, all the same concerns I had with the previous prescriptions.'' Tr. 280–81. He also observed that the prescriptions ''were filled consecutively'' and that the dispensing labels show that the same pharmacist (M.F.) filled the prescriptions, and that these circumstances would have caused him concern. *Id.* at 282–83. And Mr. Parrado further testified that he saw no evidence that the pharmacist attempted to resolve the red flags. *Id.* at 283.

The next prescription was issued on September 18, 2012 by Dr. V.S. (the same Dr. V.S. who had worked at 24th Century) to L.P. of Jacksonville, for 168 oxycodone 30. GX 3, at 7–8. Mr. Parrado testified that the prescription presented multiple red flags including ''the drug,'' the ''very high quantity,'' that the patient was ''coming from Jacksonville . . . over 200 miles'' from Tampa, and that the patient was ''paying $1,344 in

pursuant to a subpoena issue to the 24th Century Clinic and had been provided to Mr. Parrado by Government Counsel. Tr. 578, 589–90.

[30] At this point, Respondent objected, arguing that if Mr. Parrado was going to talk about this document, the Government should be required to ''produce the document so that we can see what it is that he's talking about. You know, he's talking about some amorphous document.'' Tr. 270. He also argued that the testimony was outside the scope of either cross examination or the Prehearing statement. *Id.* While the ALJ disagreed that it was outside the scope, he explained that because there was ''no document in front of him'' and he was ''relying on the frailties of human memory,'' he was not going to give this testimony ''a whole lot of weight.'' *Id.* at 271.

[31] Respondent objected to Mr. Parrado's testimony as to the price, asserting it was beyond the scope of the Pre-hearing Statement because it did not specifically identify ''the pricing issue'' as being one of the red flags associated with the prescription. Tr. 278. The Government did, however, identify that it intended to elicit testimony on the issue of ''individuals playing [sic] high prices for prescriptions . . . with cash.'' ALJ Ex. 7, at 3 (No. 15–7).

cash.'' Tr. 284. Mr. Parrado then testified that there was ''nothing documented'' regarding the pharmacist's attempt to resolve the red flags. *Id.*

After Respondent ''object[ed] to the repetitive nature of this,'' the ALJ asked Mr. Parrado if he had found ''the same kinds of red flags'' throughout the Exhibit. *Id.* at 285. Mr. Parrado answered ''[y]es.'' *Id.* The ALJ then asked Mr. Parrado if he had also found that ''the failure to resolve the red flags is documented on the documents there?'' *Id.* Mr. Parrado answered ''[y]es.'' However, after the ALJ asserted that ''[t]hat seems to address all of Exhibit 3,'' the Government advised the ALJ that there were ''some differences.'' *Id.*

The Government then questioned Mr. Parrado about two prescriptions which were issued on May 22, 2102 by Dr. C. (also of 24th Century) to L.B. of Dover, Florida, which the latter filled the same day. GX 3, at 11–14. The prescriptions were for 168 oxycodone 30 and 84 Dilaudid 8 mg. *See id.* Asked by the Government whether the combination of these two drugs raised a red flag, Mr. Parrado testified that ''that's a major red flag in that you have two immediate use opioids being dispensed at the same time. The practice is never to dispense two immediate use opioids at once, at the same time for the same patient.'' *Id.* at 286. Mr. Parrado then testified that both of the drugs were immediate release, and upon being asked if there was a way to resolve this red flag, Respondent objected to the testimony, arguing that it was beyond the scope of the Government's Prehearing Statement. *Id.* at 287.

The ALJ overruled the objection, explaining that ''I'd like to know.'' [32] *Id.* Mr. Parrado then testified that he could not resolve the red flag, and that while it was proper therapy to prescribe a ''long-acting opioid, like OxyContin'' and an immediate release drug ''such as hydromorphone for breakthrough,'' using ''two immediate use opioids[,] [y]ou just don't do that.'' *Id.* Here again, Respondent objected on the ground that the opinion was beyond the scope of Mr. Parrado's expertise because he is not a physician. *Id.* at 287–88. The ALJ overruled the objection. *Id.* at 288.

On May 22, 2012, Respondent filled prescriptions for 168 oxycodone 30 and 56 Dilaudid 8 issued by Dr. S.A.H. (of 24th Century) to V.B., who has the same last name and lived in the same town as L.B.[33] GX 3, at 15–18. Asked whether ''seeing these prescriptions together,'' there were ''additional red flags,'' Mr. Parrado testified that ''the fact that two people from essentially the same address were coming together with the same last name for the same drugs which were two immediate use opioids from the same clinic . . . I would have found that unresolvable.'' Tr. 289–90. Mr. Parrado then testified that he found no evidence that the red flags were resolved. *Id.* at 290.

On October 22, 2012, Dr. V.S. (who, according to the prescription was then working at the MD Plus Clinic in Lakeland), issued a prescription for 168 oxycodone 30 to J.P., whose address (which again was not written on the prescription) was in Ft. Walton Beach, Florida; Respondent filled the prescription the same day. GX 3, at 19–20. Upon being asked ''what kind of route J.P. [would have] follow[ed] if he came from home, went to the doctor's office in Lakeland and then went to Tampa'' to fill the prescription, Respondent objected on the ground that the testimony would be speculative because Dr. V.S. could legally prescribe at any place in the State. Tr. 293–94. After the ALJ overruled the objection, Mr. Parrado testified that while he did not ''know the exact route [J.P.] took . . . the triangle between . . . the three places is very large [and] would have to be resolved.'' *Id.*

On October 23, 2012, Dr. V.S. (of the MD Plus Clinic) issued a prescription to K.B. of Jacksonville, for 168 oxycodone 30; Respondent filled the prescription on November 7, 2012. GX 3, at 21–22. On October 22, 2012, Dr. R.R. (of the 24th Century Medical Center) issued a prescription to R.B. of Milton for 168 oxycodone 30; Respondent filled the prescription on November 1, 2012. *Id.* at 23–24. Mr. Parrado testified that both prescriptions presented the same red flags that he had previously discussed. Tr. 295–96.

On November 5, 2012, Dr. H.D. (of the 24th Century Medical Center) issued a prescription to J.S. of Panama City Beach, for 180 oxycodone 30; Respondent filled 120 tablets of the prescription the same day. GX 3, at 25–26. Asked where Panama City Beach is in relation to Tampa, Mr. Parrado testified that it is located in the ''extreme western part of the Florida panhandle'' and 450 miles from Tampa. Tr. 297.

Notably, the prescription contains a handwritten notation: ''120 per pat'' with the rest of the word obscured by the address sticker, below which is the date and time. GX 3, at 25. According to Mr. Parrado, ''this was the only form of any kind of notation or documentation I saw on any of the records showing that they did document at one point and the only thing they documented was that they shorted the person pills.'' [34] Tr. 298. Mr. Parrado further noted while the address on prescription listed Panama City Beach as J.S.'s town of residence, the sticker attached to the prescription, as well as the dispensing label, listed her town of residence as Port Charlotte, which is in the ''opposite direction'' from Tampa. *Id.*

On November 5, 2012, Dr. R.R. (24th Century) issued a prescription to A.R. for 180 oxycodone 30; Respondent filled the prescription the same day. GX 3, at 27–28. While the prescription lists the patient's address as Lawtey, Florida, both the address sticker attached to the prescription and the dispensing label list A.R.'s address as in Gainesville, Florida. *Id.* Over Respondent's objection (on grounds of no notice), Mr. Parrado testified that this was an additional red flag and the ''difference . . . should have been documented.'' Tr. 300–01.

On April 23, 2012, Dr. S.A.H. (24th Century) issued a prescription to T.P. of St. Augustine, Florida for 180 oxycodone 30; Respondent filled the prescription the same day. GX 3, at 29–30. Noting that Saint Augustine is located ''just below Jacksonville'' in ''the upper northeast corner of Florida,'' Mr. Parrado testified that ''the distance'' between T.P.'s residence and Respondent was a red flag. Tr. 301–02.

Also on April 23, 2012, Dr. P.C. (24th Century) issued a prescription to A.W. of Mayo, Florida, for 200 oxycodone 30; Respondent filled the prescription the same day. GX 3, at 31–32. Mr. Parrado testified that Mayo is located 150 to 200 miles from Tampa and that this was a red flag ''along with all the other things,'' including ''the drug and the price paid,'' which was $1,400. Tr. 302–03; GX 3, at 32.

On April 23, 2012, Dr. P.C. issued a prescription to D.T. of Gainesville for 190 oxycodone 30; Respondent filled the prescription the same day. GX 3, at

[32] As discussed above, the Government failed to provide Respondent with constitutionally adequate notice on this issue. *See, e.g., Pergament United Sales,* 920 F.2d at 135 (''The primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior.'').

[33] Mr. Parrado noted that while the prescriptions for L.B. and V.B. indicated that they lived on different streets, they had the same house number. Tr. 288. While Mr. Parrado then suggested that ''may have been just a typo,'' *id.,* the Government offered no further evidence to corroborate this testimony.

[34] Mr. Parrado further testified that it is common practice to make a note on the prescription when pharmacist does not provide a patient with the entire quantity of the prescription. *Id.* at 299.

33–34. Also on April 23, Dr. S.A.H. issued a prescription to J.S. of Tallahassee for 168 oxycodone 30; Respondent filled the prescription the same day. *Id.* at 35–36. Mr. Parrado testified that neither prescription raised ''any additional red flags'' beyond those he had previously discussed. Tr. 303. However, on further questioning, he testified that Tallahassee is 250 to 260 miles from Tampa.[35] *Id.* at 303–04.

On November 2, 2012, Dr. R.R. issued a prescription for 112 Dilaudid 8 mg to T.N., which Respondent filled the same day. GX 3, at 37–38. Of note, while the prescription as prepared by Dr. R.R. listed T.N.'s address as being in Port Salerno, Florida, both the address sticker placed on the front of the prescription and the dispensing label listed an address in Gainesville. *See id.* Mr. Parrado testified that this was a red flag, as was the high dose of the prescription (32 mg per day), which was ''above the 24 milligram upper dose recommendation.'' Tr. 304.

The final prescription in the exhibit was issued on November 5, 2012 by Dr. H.D. to K.P. of Spring Hill for 140 Dilaudid 8 mg. GX 3, at 39–40. Asked the same question as with previous prescription (''How about the drug and the amount?''), Mr. Parrado testified: ''[t]he answer will be the same.'' Tr. 304. Thereafter, the Government moved Exhibit 3 into evidence in the Superior II matter, and the ALJ admitted the exhibit. *Id.* at 305.

The Government then moved to admit into evidence its Exhibits 4 and 14. *Id.* The former is a compilation of 25 additional prescriptions for oxycodone 30 and Dilaudid 8 mg, which was offered to show additional instances in which patients presented the ''red flag of long distance'' between their residence, the prescriber, and Superior II. *Id.; see also* GX 4 (No. 15–7). The latter is a collection of MapQuest maps and printouts showing the distances between the patient's residence, the prescriber, and Superior II. *Id.; see also* GX 14 (No. 15–7). Both exhibits were admitted over Respondent's objection.[36] Tr. 305–06.

As for the prescriptions in GX 4, Mr. Parrado testified that they all presented the red flag of the patients travelling long distances. Tr. 308. He further testified that he used Google to ''get an approximation of the mileage'' for those cities for which he did not know the exact mileage. *Id.* at 310.

Asked by the Government whether he had seen any evidence that Superior II's pharmacists attempted to resolve the red flags presented by the prescriptions in both its Exhibits 3 and 4, Mr. Parrado testified that ''[t]he only documentation I saw was that shortage of tablets. That's the only thing I saw documented anywhere.'' Tr. 312. With respect to these prescriptions, Mr. Parrado then testified that he did not ''see any evidence'' that the dispensing pharmacist had complied with his/her corresponding responsibility to ensure that prescriptions were issued for a legitimate medical purpose. *Id.*

The Government concluded its direct examination of Mr. Parrado, asking him—over Respondent's objection—whether the pharmacists, who filled the prescriptions in GXs 3 and 4, ''knew or had reason to know that the prescriptions were being issued without a valid doctor/patient relationship?'' *Id.* at 313–14. Mr. Parrado answered:

> All these red flags would have caused me concern to where I had to call that physician to verify all these things.
>
> And at that point I would have to use my professional judgment and whether or not even though possibly faced with what could ostensibly be a valid prescription I should know or either knew or should have known that these were being used . . . for not a legitimate medical purpose, just based on all the red flags that are present.
>
> So even if the doctor had told me, yes, he did fill it, I would still, I still would not have filled them.

Id. at 314–15.

On cross-examination, Mr. Parrado adhered to his earlier testimony that if the resolution of a red flag was not documented on the prescription, ''it wasn't done.'' *Id.* at 316. While Parrado acknowledged that he did not know whether Florida law requires that this be documented on the prescription, he testified that ''[i]t's been standard practice since I've been practicing for 43 years.'' *Id.* He further acknowledged that DEA does not require that the resolution of a red flag be documented on the face of the prescription. *Id.* at 318. And he also acknowledged that in rendering an opinion as to whether another pharmacist had properly exercised his professional judgment in deciding to dispense a controlled substance, it is important to understand the circumstances, including whether the pharmacist has a history with the prescriber of the prescription. *Id.* at 321.

Asked by Respondent whether he ''wouldn't think twice about'' a prescription he received from a reputable prescriber which was missing the patient's address, Mr. Parrado testified that ''I would do something to address that and fix it.'' *Id.* Asked if he would then go into his pharmacy software and use the information to put an address label on the prescription and that this would not cause him ''to be concerned about diversion,'' Mr. Parrado answered: ''Not if I knew the patient. And there's always a circumstance where it [the prescription] could be good.'' *Id.* at 321–22.

When then asked whether ''one of those circumstances would be if you knew the prescribing practitioner and . . . . [his] practice[] and . . . protocols and . . . knew that when you called them [he] answered your questions about the diagnoses and the reasons for things,'' the ALJ, without any objection by the Government, stated that he would not allow Mr. Parrado to answer the question because there was ''no evidence that the Respondent, through any of its pharmacists, did that.'' *Id.* at 322. Even after Respondent argued that it was a hypothetical question and that Mr. Parrado ''was proffered as an expert'' and had testified that he had asked for additional information from DEA and been denied it, the ALJ adhered to his ruling. *Id.* at 322–23.

However, Mr. Parrado subsequently agreed with Respondent that in trying to determine whether a red flag had been resolved, it is ''important to know what the pharmacist knew about'' the patient. *Id.* at 324. Mr. Parrado testified that he had asked for the patient profiles for the Superior II patients and that the Government told him not to look at those. *Id.* at 324–25. Mr. Parrado then acknowledged that a patient profile would show the complete history of prescriptions filled by the pharmacy in the period for which it was run and would show whether the patient was also receiving non-controlled drugs. *Id.* 325. He also acknowledged that the patient profile would be important in

[35] Respondent objected to Mr. Parrado's testimony regarding the distances from Mayo to Tampa and Tallahassee to Tampa on the ground that this testimony was not disclosed in advance of the hearing. Tr. 302–03. In its Pre-Hearing Statement, the Government did disclose that Mr. Parrado ''will . . . testify regarding large quantities of oxycodone distributed by Respondent on April 23, 2012, to at least twelve persons . . . and four of them (T.P., A.W., D.T., and J.S.) resided more 100 miles from Respondent's pharmacy.'' ALJ Ex. 7, at 5 (No. 15–7). Respondent thus had notice that the distance between it and the residences of the patients would be at issue even if the Government did not disclose that Mr. Parrado would testify as to the precise distances.

[36] With respect to the MapQuest printouts, Respondent did not object based on authenticity, but rather on lack of foundation, arguing that ''there are ways to set parameters to avoid highways, to take the shortest route, to take the fastest route.'' Tr. 307. The objection is not without some merit. However, given the distances of the patients from the prescribers and Superior, any differences in mileage or driving time which would be caused by choosing between these two parameters is not significant enough to be material.

determining whether the patient was opioid naïve or tolerant. *Id.*

Mr. Parrado then testified that he was given some ''partial medical records,'' and that these showed that ''these people were on multiple controlled substances [and] not just the prescriptions that were given to me.'' *Id.* He then added that there were ''multiple people from the same address getting the exact same cocktails of these drugs.'' [37] *Id.* at 325–26.

Asked if his opinions were based on these medical records, Mr. Parrado testified that the medical records did not form his opinions but ''just reinforced'' them, because he did not ''see any documentation of conversations between the pharmacy and the clinic'' and the records ''showed on a lot of these patients the cocktails.'' *Id.* at 326. After Mr. Parrado testified that the medical records were those ''of the prescribing physician,'' Respondent attempted to ask if he knew whether a physician is supposed to note a conversation with the pharmacist in the chart. *Id.* The ALJ barred the question, even in the absence of an objection of the Government, reasoning that there was no evidence that any of Superior II's pharmacists had called the prescriber. *Id.* at 327.

Mr. Parrado then acknowledged that there is ''no upper limit on the amount of an opioid that a patient can develop a tolerance to'' and that there is no federal limit on the quantity of a drug that can be prescribed. *Id.* He further testified that whether a prescription is medically necessary is patient specific and depends on such factors as tolerance, the condition causing the pain, and the duration, intensity and frequency of the pain. *Id.* at 330.

Asked whether it was *per se* unlawful to fill an oxycodone 30 prescription, Mr. Parrado testified that ''I would have to evaluate each prescription individually and know that . . . that patient had developed that tolerance . . . before I fill it.'' *Id.* at 331. Then asked whether ''[o]xycodone 30 standing alone is not an indicator that a prescription'' lacks a legitimate medical purpose, Mr. Parrado answered: ''Well, it's the leading drug of abuse on the street. So that is the first potential for a red flag.'' *Id.*

Mr. Parrado acknowledged that patients have the right to pay for their prescriptions in cash and that in some States, the law requires a pharmacy to allow a patient to pay in cash. *Id.* at 332. Mr. Parrado then testified that it is ''not so much the paying cash, it's the quantity of cash that raised the red flag to me.'' *Id.*

While Mr. Parrado agreed that physicians may use a particular drug as their default option in treating a patient such as in prescribing a cholesterol-lowering medication, he disagreed that this practice also applies to pain management. *Id.* at 333. As he explained: ''how you treat diabetes, blood pressure, . . . cholesterol therapy, those are relatively standard therapies. But not in pain, pain has to be individualized, starting low and going slow as you reach the proper limit'' of dosing. *Id.* Respondent then asked if the fact that a prescriber tends to prescribe one drug over another for pain patients ''is not necessarily indicative of diversion, is it?'' *Id.* at 334. Mr. Parrado answered: ''It becomes a cause for concern when it's always the number one known drug of abuse on the streets. That's where it becomes a concern. And in oxycodone and Percocet, there's a very low dose, it's only five milligrams, whereas . . . oxycodone 30 presents a different issue.'' *Id.*

Asked if when he verified the identity of a person filling a prescription, he would place a photocopy of the patient's identification on the prescription, Mr. Parrado acknowledged that ''[a] lot of times we did,'' or we had ''another page with it,'' or we ''scanned it into our computer where it showed up as part of that patient's profile.'' *Id.* at 336. When, however, Respondent asked Mr. Parrado if ''it would be appropriate for certain types of verifications and resolving of red flags to keep, say for example, a photo ID in an electronic file of a pharmacy, particularly in the age of computers,'' the ALJ intervened—again, in absence of an objection by the Government—and disallowed the question, explaining that ''whether it's appropriate or not, there is nothing before me that suggests that that was kept.'' *Id.* at 337.

Mr. Parrado subsequently agreed with Respondent that ''not every failure to catch a red flag is intentional'' and that pharmacists can make mistakes. *Id.* at 337–38. While he agreed that a pharmacist may make mistakes in dispensing drugs, he then explained:

> The question is that it doesn't happen over and over and over and over, which was my concern in this case and the records I was looking at. Could a person come from a long distance once? Sure. Does it happen every day from a long distance multiple times? No.

Id. at 338.

Turning more specifically to the prescriptions filled by Superior II, Mr. Parrado reiterated that he did not interview any of the patients or prescribers, as well as that DEA did not provide him with any statements made by the patients or information about the patients' conditions. *Id.* at 339. Asked whether it would be appropriate for a pharmacist, who knew the address placed on the prescription by the prescriber was incorrect, to verify the patient's address and place a sticker on the prescription with the correct address, Mr. Parrado answered: ''I would want to document that I had . . . addressed that question . . . and then put [the sticker] on there.'' *Id.* at 341. He then maintained that while the stickers were placed on the prescriptions, he did not know that the pharmacists had verified the patients' addresses. *Id.* Asked whether it is appropriate for a pharmacist to add the address to the prescription when the physician did not include it, Mr. Parrado testified: ''[a]fter consultation with the physician.'' *Id.* at 342. When then asked if a DEA letter addressing the prescribing of schedule II drugs ''says that,'' Mr. Parrado testified that Florida law (Chapter 893) ''says that you verify with the prescriber,'' before acknowledging that a DEA letter ''does not say that.'' *Id.*

Mr. Parrado agreed with Respondent that it would be permissible for a physician to prescribe pain medicine to ''two people who share a residence'' and who ''have chronic pain due to a car accident.'' *Id.* at 343–44. Asked whether ''if the prescriptions were legitimate, it would be permissible for a pharmacy to fill'' them, Mr. Parrado answered that it would be as long as the pharmacist had resolved the red flag and documented it. *Id.* at 344.

As for the ''partial medical files'' he reviewed, Mr. Parrado could not answer as to how many of them were for Superior II's patients. *Id.* at 344. As for why he was provided with partial and not the full files, Mr. Parrado explained that it was his understanding that the files ''came from the Respondent to DEA who sent them to me.'' *Id.* at 345.

Mr. Parrado acknowledged that as long as a prescriber is registered within a State, he can prescribe from anywhere in the State. *Id.* at 346. He then acknowledged that he had not looked into whether any of the prescribers had issued the prescriptions from locations other than where they were registered. *Id.* at 347.

Regarding the prescription issued to J.S. for 180 oxycodone 30 but which was only filled for 120 tablets, *see* GX 3, at 25, Mr. Parrado acknowledged that a pharmacist can change the quantity in consultation with the prescriber. Tr. 347. As for the prescription issued to T.N. for Dilaudid which listed her address as Port Salerno but the address

[37] No evidence established what the cocktails were, let alone the strength and dosing of the drugs.

and dispensing labels listed her address as Gainesville, GX 3, at 37–38; Mr. Parrado agreed that the prescription did not present the red flag of a different address when it was presented to the pharmacy and that the sole red flag was the distance.[38] Tr. 352. He then agreed that ''it is not a red flag for a pharmacist to affix the correct address to a prescription that contains an incorrect address,'' before adding that he ''would have documented'' his reason for ''changing the address.'' *Id.* at 353. However, on re-direct regarding the same exhibit, Mr. Parrado testified that if a patient presents a prescription which lists a different address for the patient from that in the pharmacy's records, this needs to be investigated and there was no evidence that the disparity was investigated. *Id.* at 362.

After Mr. Parrado noted that some of the partial medical records contained an opioid contract that required the patient to fill the prescriptions at one pharmacy, that being Respondent, he then acknowledged ''that there are a number of experts who believe that the one doctor, one pharmacy, one patient is the best way to prevent diversion when it comes to pain management.'' *Id.* at 355. And he agreed that ''[a]s long as everybody's doing their obligations,'' this approach is in ''the best interests of the patient.'' *Id.* He also acknowledged that Florida law requires the use of a pain management contract, and that the contract is supposed to identify where the prescriptions will be filled. *Id.* at 356.

Evidence Regarding the Audits and Recordkeeping Allegations

Next to testify for the Government was a Diversion Investigator (DI) who participated in the execution of the Administrative Inspection Warrant at Superior I. *Id.* at 370–71. The DI testified that at the time of the hearing, he had been a Diversion Investigator for more than five years and that he had conducted approximately 130 pharmacy inspections. *Id.* at 368–69. He also testified that he had received training in how to conduct controlled substance audits as part of his training to become a DI. *Id.* at 390.

According to the DI, ''we collected original prescriptions,'' as well as DEA 222s (schedule II order forms), invoices and inventory records. *Id.* at 372. He also ''conducted the closing inventory'' and ''helped package the documents and all controlled substance related records.'' [39] *Id.* The DI testified that he conducted an audit of Superior I's handling of controlled substances and prepared a computation chart. Tr. 373; *see also* GX 4 (No. 15–6).

With respect to the closing inventory, the DI testified that this involved a count of the drugs the pharmacy had on hand at the time of the inspection and that he was assisted by the pharmacist in performing the closing inventory. *Id.* at 373–74. He also testified that he used the pharmacy's ''bi-annual [sic] inventory'' which was dated May 2, 2011 (beginning of business),[40] and used this as the beginning date of the audit. *Id.* at 374–75. As for the closing inventory, the DI testified that he counted the drugs on hand ''with the pharmacist,'' and that the pharmacist attested to the accuracy of the inventory. *Id.* at 376. The DI further testified that after the warrant was executed, he requested additional records through the lead Investigator because ''the bi-annual [sic] inventory'' which was provided by Superior I when the warrant was executed ''did not include all the drugs that were a part of the audit.'' *Id.* at 378. On February 11, 2013, the DI received additional inventories which included ''the bi-annual [sic] inventory and . . . an in-house inventory conducted by the'' pharmacy. *Id.* at 379.

The DI then explained that in conducting the audit he reviewed the purchase records, ''the distribution transfers,'' ''any returns,'' and ''any disposition records'' which included the actual prescriptions.'' *Id.* at 378, 410. Subsequently, with respect to the prescriptions, he supervised a team which computed the dispensings, which were counted on a monthly basis. *Id.* at 412–13. The DI also explained that each of the team members was a DI, and as such, had been trained in how to conduct an audit. *Id.* at 414.

According to the DI, ''we use whatever we have as well . . . to make cross checks and to verify that there are no inconsistencies.'' *Id.* at 378. Still later, the DI explained that he personally cross-checked some of the monthly dispensing totals. *Id.* at 412.

The DI testified that his audit found that Superior I had shortages of multiple drugs. *Id.* at 380–382. The most significant of these were the shortages of 15,560 dosage units (du) of oxycodone 30 mg and 11,951 du of hydromorphone 8 mg. GX 4 (No. 15–6). In addition, the audit found that Superior had shortages of 946 du of hydromorphone 4 mg, 864 du of methadone 10 mg, 474 dosage units of morphine sulfate 100 mg ER, and 447 du of morphine sulfate 30 mg ER.[41] *Id.*

The DI also testified regarding the manner in which Superior I kept its Schedule II order forms (DEA 222). According to the DI, one of the order forms (GX 5, at 2) should not have been used because the pharmacist had lined out the National Drug Code (NDC) number for the drug being ordered and added a new NDC number. Tr. 383–84; *see also id.* at 386. The DI testified that according to 21 CFR 1305.15(a)(2), ''any alteration or any erasure or change of description should be a cause for a DEA 222 form not to be used.'' *Id.* at 383. The Government then asked the DI whether a second order form (GX5, at 3) was filled out properly. *Id.* at 384. The DI answered ''[n]o,'' and explained that ''the information in regard to the number of package[s] receive [sic] . . . was omitted.'' *Id.*

On cross-examination regarding the altered order form (GX 5, at 2), the DI conceded that according to the regulation, the manufacturer should not have filled the order. Tr. 387. Then asked whether there was ''any problem with the pharmacy having corrected the Form 222, or is the problem that the manufacturer filled the order,'' the DI explained that ''the regulation says any alteration, any erasure, and that should not be used.'' *Id.* at 387–88. When then asked if it is unlawful to make a mistake on the form, the DI testified ''[t]he regulation is clear on how to use DEA 222 forms. And [the] DEA 222 form[] states that it should not be filled.'' *Id.* at 388.

On cross-examination regarding the audit, Respondent's counsel asked the DI if there were any spreadsheets that showed how the DEA 222s were counted and how the dispensings were counted. Tr. 393. The DI answered: ''No, I don't have that at this time, sir.'' *Id.* Then asked whether he had ever had such documents ''at any time,'' the DI answered: ''I do not recall at this time if I have this or not.'' *Id.*

Respondent's counsel then represented that when DEA provided Respondent with the CDs (which contained the records obtained from them) after the Order to Show Cause was served, the CDs included ''some scratch papers.'' Tr. 393. Counsel then

[38] Contrary to the question, Mr. Parrado had earlier identified the dosage as a red flag. Tr. 304.

[39] Asked whether he had any knowledge as to whether Superior I's computer records were electronically copied, the DI testified that while he did not handle that, he believed that digital evidence was collected. Tr. 372.

[40] The DI subsequently explained he used the inventory which must be taken every two years (*i.e.,* the biennial), ''which is required . . . per regulation 1304.11.'' Tr. 374.

[41] The audit also found an overage of 159 du of morphine sulfate 60 mg ER. GX 4 (No. 15–6).

asked the DI if he ''recall[ed] working out some scratch papers where you may have done the math?'' *Id.* at 393–94. Counsel also advised the ALJ that he had copies if it would refresh the DI's recollection. *Id.* at 394. After the DI answered that he did ''not recall this,'' Respondent's counsel asked the DI if it would ''refresh [his] recollection if [he] looked at the notes?'' *Id.* The ALJ then intervened, stating: ''Documentation, even if it does, this documentation is not going to be allowed.'' *Id.* When Respondent's Counsel then argued that ''it's just for impeachment,'' the ALJ explained that while Respondent's Counsel could impeach the witness, he could not use documents which he did not provide ''ahead of time'' and that he had ''an obligation to provide [the documents] as part of the response to the Pre-hearing Statement.'' *Id.* at 394–95.

Respondent's counsel then asserted that the documents were ''not intended to be used as an exhibit'' but ''merely to check the math.'' *Id.* at 395. He further asserted that when he went ''through the DEA 222s on the [m]orphine [s]ulphate tabs and add them up, all the ones that were were returned . . . by the Government, I get to a number of 7,200. And what I'm trying to figure out is whether or not there are any supporting documents where we can see your math to see if you got it correct.'' *Id.* After the Government objected that Respondent's counsel was testifying and the ALJ expressed his agreement with the Government, Respondents' counsel stated that he wanted to present the 222s to the DI and ''walk through the math together and see if Your Honor comes to the same number that they [sic] do.'' *Id.* at 396. The ALJ ruled that because Respondent's counsel ''didn't [timely] present the 222s as evidence,'' he would not allow the question. *Id.*

Then asked whether he did his calculations ''by hand'' or by creating a spreadsheet, the DI testified that he could not recall what procedure he used because he did the audit two years earlier. *Id.* at 396–97. Asked if he used only the hard copy 222s or also used the electronic order records, the DI testified that he ''used all the DEA 222s that were there[] and there were some CSOS'' (electronic orders) as well. *Id.* at 397. The DI subsequently explained that the electronic orders were printed out and that he used the paper copy of these. *Id.* at 401. Then asked whether he did anything to control for math errors, the DI testified that he ''reviewed [his] counts on many occasions'' and ''did some cross checks'' with ''other documents provided by the pharmacy.'' *Id.* at 402. The DI also testified that he cross-checked Respondent's purchases by using ARCOS data,[42] but because some distributors report only every quarter, he could only check approximately 95 percent of the purchase data. *Id.* at 402–04.

The Government called another DI, who testified regarding the execution of the AIW at Superior II and the subsequent audit of its handling of controlled substances. *Id.* at 469, 471. The DI testified that she delivered the warrant to the pharmacy manager and did a closing inventory. *Id.* at 471. She then asked for the purchasing records and the hard copy controlled substance prescriptions. *Id.* at 472. The DI testified that she was familiar with patient profiles and that no patient profiles were obtained during the execution of the warrant. *Id.* at 473.

The Government then asked the DI about a number of Superior II's schedule II order forms. *Id.* at 473–74. Regarding the orders forms in GX 6 (No. 15–07), the DI testified that the forms were not filled out properly, as ''[t]hey are missing the number of packages received and date received on some of the lines on each form.'' *Id.* at 474. With respect to the first form in the exhibit, which had two line entries, each for 12 packages of 100 count of oxycodone 30, she identified line two as not being properly completed, apparently because it did not list the number of packages received and the date received. *Id.*

Turning to the second form, she also identified the second line of the form as not being properly completed, apparently because it did not list the number of packages received and the date received. *Id.* However, the first two forms have the same serial number, thus establishing that one of them is a duplicate. *Compare* GX 6, at 1, *with id.* at 2.

As for the next four forms, the DI testified that each was a copy and not the original and was thus a violation. Tr. 474–75; *see also id.* at 521. With respect to several of the remaining forms in the exhibit, she identified that for several of the line items there was no notation that ''no packages [were] received or date received.'' *Id.* at 475; *see also id.* at 476.

However, on cross-examination, the DI testified that she relied on the entries on the forms maintained by Respondent and did not verify whether every line on the 222s had been actually shipped by the distributors. *Id.* at 518. While the DI acknowledged that sometimes distributors don't ship an entire order at once, she then testified that ''after 60 days, the 222 is invalid'' and the purchaser ''should go back and put a zero and the date they put the zero'' on the form. *Id.* at 520. However, when asked where, in the *Pharmacist's Manual,* it instructs registrants to do this, the DI answered: ''I couldn't tell you which page. But it does say they have to complete the 222 forms.'' *Id.* When then asked where in the regulation it says that, the DI stated that she did not ''know the specific quotation.'' *Id.*

Moving back to the audit, the DI testified that ''we asked for purchasing records [43] and dispensing records, and that the hardcopy original prescriptions [44] were used as the dispensing record.'' *Id.* at 477. As the starting point of the audit, the DI testified that she ''asked when their last physical count was. And we used the July 31st, 2012. And the pharmacist got the numbers from their perpetual inventory.'' *Id.* On cross-examination, the DI reiterated her earlier testimony that she ''did not ask for perpetual inventory numbers. I asked for an actual physical count of those seven drugs.'' *Id.* at 491. She then explained that Superior II's employees ''told me that they take physical counts very frequently'' and that she ''asked them when their most recent one was that was at least six months'' old, ''[a]nd these were the numbers I was given.'' *Id.* at 491–92. As for the closing inventory, the DI testified that the pharmacist ''counted the pills, and I witnessed.'' *Id.* at 477.

According to the DI, the audit found that Superior II was short 40 du of hydromorphone 4 mg and had an overage of 2,576 du of hydromorphone 8 mg. *Id.* at 479. As for the other drugs, the audit found overages of 1,189 du of oxycodone 30 mg, 896 du of methadone 10 mg, 674 du of morphine sulfate 30 mg, 563 du of morphine sulfate 60 mg, and 426 du of morphine sulfate 100 mg. GX 12. According to the DI, ''[a]n overage indicates that all records either

[42] *See* 21 CFR 1304.33 (setting forth ARCOS reporting obligations imposed on manufacturers and distributors).

[43] On cross-examination, the DI testified that she used both the paper and electronic 222 forms in doing the audit. Tr. 504. She also testified that ''[w]e always ask if there's been any theft or loss, returns, or if they have any outdated drugs.'' *Id.* She then testified that she specifically recalled asking a pharmacist for these records. *Id.* at 505.

[44] The DI testified that she asked for the hard copy Schedule II prescriptions for the period of January 1, 2011 through October 31, 2011, and from December 1, 2012 to the date of the warrant, February 4, 2013. Tr. 515. She also testified that ''I asked for specific date ranges, because there had been a notice of inspection prior to the admin. inspection warrant. So I asked for different date ranges.'' *Id.* at 514. The DI then explained that she did not participate in the prior inspection. *Id.*

were not maintained or not provided.'' Tr. 480.[45]

On cross-examination, the DI testified that she did not do any interviews and was not present during any interviews. *Id.* at 485. She further testified that she did not notify Superior II of the audit results and did not know whether another DI had done so. *Id.* at 486. She also testified that she did not do any further investigation into Superior II other than to review the records that were obtained and to complete the audit. *Id.* at 487.

On further cross, the DI testified that in performing the audit, she did not compare the 222 forms she obtained from Superior II with those its suppliers provided to the Agency.[46] *Id.* at 501. She also testified that she could not recall if she obtained ARCOS data to verify whether the documents obtained pursuant to the warrant contained ''accurate information,'' explaining that ''[w]hen we conduct [an] audit, it is the registrant's responsibility to provide all documents.'' *Id.* at 502. Subsequently, the lead investigator on the matter testified that she did not instruct anyone working on the investigation to ''consult ARCOS'' or to look at either the paper or electronic 222 forms that had been sent to the Agency.[47] *Id.* at 583.

The DI further testified that she kept track of the serial numbers on the 222s by spreading them out on a desk but did not ''make a document.'' *Id.* at 505. Respondent's counsel then asked her if she had considered several orders which he identified by drug, quantity, date, and the order form number. *Id.* The DI responded to these questions stating that if the record was provided, it was considered. *Id.* at 505–08.

Subsequently, the DI acknowledged that pharmacy personnel filling a prescription could make an error when counting the pills. *Id.* at 512. She then identified another DI who was involved in calculating the dispensing totals for the audit, as well as the pharmacy's receipts. *Id.* at 513.

The Government's final witness was a DI from the Tampa office with 19 years of experience as such, who was the lead investigator in the Superior II matter. *Id.* at 539–40; 558. She testified that on November 30, 2012, she participated in a Notice of Inspection at Superior II, which she explained involved ''go[ing] on-site and advis[ing] the registrant that we're going to be doing an audit of their controlled substance records.'' *Id.* at 541. She further testified that during the Notice of Inspection issued to Superior II, ''[w]e obtained records, purchase records, and dispensing records which consisted of the prescriptions.'' *Id.*

The DI testified that she was not present at Superior II when the AIW was executed. *Id.* at 542. However, she did review the records seized from Superior II to include its purchases and dispensing records. *Id.* at 543. She also testified that no patient profiles were taken during the November 30 inspection and that when she reviewed the records obtained from Superior II pursuant to the AIW, she did not see any patient profiles. *Id.* at 544. Subsequently, she testified that the records she told Mr. Parrado that he could not review were the records she obtained from the State's Prescription Drug Monitoring Program. *Id.* at 546–48. And later, on cross-examination, she clarified that Mr. Parrado did not get the PDMP records. *Id.* at 559. She also testified that she did not provide the ''partial medical records'' to Mr. Parrado, *id.* at 577, and that the records were provided by Government Counsel.[48] *Id.* at 578.

Thereafter, the DI acknowledged that various notations made on the Superior II order forms were her initials and that she did not keep a clean copy of the documents. *Id.* at 549. According to the DI, when she reviews records, she ''will usually initial it in some way or the other just to let me know that I did review that record.'' *Id.* She testified that the 222s that were returned to Respondent had her initials on them. *Id.* at 550.

Turning to Superior's II ordering of controlled substances using the Controlled Substances Order System (CSOS), the DI testified that during the November 30, 2012 inspection, she met with a pharmacist (Mr. Majed) and asked to see its primary records for the receipt of controlled substances. *Id.* at 551. According to the DI, Mr. Majed stated ''that once he gets the orders he inputs it into the system[,] . . . places the order[,] . . . then . . . prints out'' the form, and upon receipt of ''the product, he jots it down where it says packages shipped and packages and dates shipped. So I said this is your receipt. After you receive them manually,'' at which point Respondent objected.[49] *Id.* at 551–52. After the ALJ overruled the objection, the DI testified that when she asked Mr. Majed what he did once he received product, Mr. Majed said that ''he notates [the receipt of product] on this paper form'' and that he did not go back into the CSOS and enter the receipt because ''he wasn't aware that he had to do that.'' *Id.* at 554. She then asked Mr. Majed if the paper records were the ''primary records'' and was told ''yes.'' The DI then testified that these were the records she used for the audit. *Id.*

Continuing, the Government asked the DI whether a printout of an electronic 222 form complied with DEA regulations. *Id.* at 555. According to the DI, the document ''should have been linked'' and was the ''supplier's copy'' and not the ''purchaser's copy.'' *Id.* at 556. The DI further explained that ''[y]ou see where it says packages shipped? He's not the supplier. He's the purchaser. So that should be packages received and date received. What he's showing me here is the supplier's copy.'' *Id.* Moreover, to the DI's knowledge, this record was not included in any database. *Id.*

The DI further explained that in order for a person to use the CSOS, the person has to have a pass key. *Id.* at 556–57. However, while Mr. Majed represented that he had a key, the DI subsequently determined that he did not, and that only Mr. Obi (the owner) and another

[45] Respondent objected to the admission of the computation chart, arguing that the opening inventory was based on Superior II's perpetual inventory, which it is not lawfully required to maintain. Tr. 483. The ALJ overruled the objection. *Id.* While there is no requirement to maintain a perpetual inventory, there is no requirement that the Government use only an actual hand counted inventory in establishing the quantities on hand on the beginning date of the audit period. Indeed, at times, a pharmacy is entirely missing the required inventory and the DIs use zero as the opening inventory.

Most significantly, Respondent ignores that the DI testified multiple times that she asked for an actual physical count which was at least six months old and used what Superior II gave her.

[46] Pursuant to 21 CFR 1305.13(d), ''[t]he supplier must retain Copy 1 of the DEA Form 222 for [its] files and forward Copy 2 to the Special Agent in Charge . . . in the area in which the supplier is located.''

[47] The evidence also showed that only the DI and the lead DI ''handled the prescription records and the 222s.'' *Id.* at 584.

[48] Later, on re-direct, the Government asked the DI if she had ''ever subpoenaed any medical records from any clinics owned by Mr. Obi-Anaduime?'' Tr. 589–90. The DI testified that ''[o]n the same day of the administrative inspection warrant, we issued subpoenas for the clinic, 21st [sic] Century.'' *Id.*

[49] Respondent objected on the grounds of hearsay and the lack of notice. As for the latter objection, this was based on the Government having been ''aware of [Mr. Majed's] participation in this and [it] gave us no notice in [its] pre-hearing statement that [it] intended to have this witness testify about things that he said.'' Tr. 552. Respondent did, however, have notice of the issue through the Government's disclosure of the DI's testimony. ALJ Ex. 6, at 6–7 (No. 15–7) (''She will testify that Respondent, as a purchaser of controlled substances *via* [the CSOS], failed to create an accurate record of the quantity of controlled substances received and the date received. She will testify that Respondent failed to electronically archive and link these records to the original order, as required by the . . . [r]egulations.''). As for Respondent's objection that the testimony was hearsay, hearsay is admissible in these proceedings and Respondent made no argument as to why the testimony was unreliable.

pharmacist (Ms. Minozzi) had pass keys. *Id.* at 557–58.

On cross-examination, the DI acknowledged that because she had the PDMP records she could determine whether the patients were opioid tolerant or opioid naïve. *Id.* at 559–60. The DI did not, however, use that information. *Id.* at 560.

The DI further testified that electronic 222 forms found in Government Exhibit 7 were obtained during the AIW, when she was not present. *Id.* at 563. When then asked whether her testimony regarding the statements made by Mr. Majed were based on her personal knowledge, the DI testified that they were made during the notice of inspection. *Id.*

The DI also testified that Mr. Majed told her that the handwritten notations on printouts of the electronic 222 forms were of the packages that the pharmacy had actually received and the date received. *Id.* at 567. The DI testified that if Superior II pharmacists had correctly documented their receipts of drugs, ''they would have printed out the receipt and the receipt date'' on a different form and not used the supplier's copy. *Id.* The DI then testified that the receipt record must be electronically linked to the same record that the pharmacy used to place the order. *Id.* at 569.

Respondent's counsel further attempted to ask the DI if she had investigated if Superior II had stopped ordering oxycodone after the AIW. *Id.* at 574. While the Government objected that the question was outside the scope, the ALJ initially overruled the objection. *Id.* However, after Respondent re-asked the question with only an immaterial change in wording, the ALJ barred the question, on the ground that Respondent had not acknowledged any misconduct in its Pre-hearing Statement. *Id.* at 575–77.

Before the Government rested, it requested a ruling from the ALJ clarifying whether Respondents would be allowed to call any witnesses. *Id.* at 594. After the ALJ stated that he agreed with the Government's understanding that Respondents would not be allowed to call any witnesses, Superior II's counsel stated that he intended to call a witness. *Id.*

Asked by the ALJ to provide ''the legal basis for . . . Superior II to produce any witnesses, given [his] prior orders,'' Superior II's counsel stated that ''we have noticed witnesses in the Pre-hearing Statement,'' including Mr. Obi-Anadiume. *Id.* at 595. Again asked to explain the legal basis for calling any witnesses, Superior II's counsel argued that in its Prehearing Statement, it notified the Government that it intended to call ''any and all witnesses identified in the Government's Pre-hearing Statement.'' *Id.* at 597. As to the issues that Mr. Obi would testify to, Superior II's counsel argued that ''the summary of [his] testimony'' was ''covered sufficiently'' by the Government in its Prehearing Statement and that ''the Government has no prejudice with respect to this.'' *Id.* at 597–98. Superior II's counsel then asserted that because Government counsel had represented in its Prehearing Statement that it intended to call Mr. Obi and had subpoenaed him, he should be allowed to testify. *Id.* Superior II's counsel further argued that under section 555 of the Administrative Procedure Act, Mr. Obi was an interested person who had the right to participate in the proceeding, and that ''fundamental fairness'' required that he be allowed to testify. *Id.* at 598–602.

After Superior II's counsel represented that he was making the same motion with respect to Superior I, the ALJ asked if he was relying on the Government's Prehearing Statements as his proffer. *Id.* at 604. Superior II's counsel advised that there was one additional matter that went beyond the scope of the proposed testimony—''the acceptance of responsibility and corrective action.'' *Id.* at 604. Superior II's counsel further represented that he had ''submitted written information to [Government Counsel] with language of proposed acceptance of responsibility and with specific corrective actions that have already been taken, and those that are being taken and those that will be taken in the future.'' *Id.* at 605.

The ALJ denied the motion, noting that the proffer ''clearly . . . exceed[ed] what the Government presented in its Pre-hearing Statement.'' *Id.* at 606. Continuing, the ALJ stated:

> With all due respect to your colleagues, I think these were well informed lawyers making strategic decisions to keep as little information in the Pre-hearing Statements as possible. And I think it ill-served the course of justice and makes this proceeding a much more difficult process merely because of a strategic decision to keep me in the dark.
>
> I'm not attributing that to you at all. And I don't expect a response, nor will I care to hear a response with respect to that. I've already given Mr. Sisco the opportunity to explain why the record is as it is in documents that I've received from Respondents.
>
> And that record will stand, I will address that at another time in another forum. But from what you've told me, I don't see a legal justification for allowing the Respondent to, in either case . . . present testimony.

Id.[50] The ALJ thus denied Respondents' motion. *Id.* at 606–07.

Superior II's counsel then sought to allow Mr. Obi to testify by asking and ''answering the questions [himself] that are posed in the Government's Pre-hearing Statement.'' *Id.* at 608. The ALJ denied the request. *Id.* Superior II's counsel then sought to take an interlocutory appeal of the ALJ's ruling. *Id.* The ALJ denied the motion. *Id.*

Explaining that he wanted to understand how the proffer would be done, Superior II's counsel then asked the ALJ if he wished for him ''to proffer what would be said'' by Mr. Obi. *Id.* at 609. The ALJ responded ''no,'' and explained that Superior II's counsel had given him the ''substance of what that information would be.'' *Id.* Superior II's counsel then argued that he should be allowed ''to put the full proffer . . . on the record.'' *Id.*

In response, the ALJ stated that Superior II's counsel had made ''a sufficient proffer,'' noting that he had sought to go ''beyond the scope of what the Government covered and enter[] into the area of acknowledgment and remediation [which] would not be permitted[,] [b]ecause you did not disclose it in advance.'' *Id.* at 610. The ALJ then stated that this told him ''the broad parameters'' and that was all he needed ''to preserve your client's right.'' *Id.*

Superior II's counsel then explained that his ''statements about the Government's Pre-hearing statement and the broader subject matters [was] not the proffer [and] that the proffer is substantially broader [as] it addresses individual patients, because the Government's Pre-hearing Statement called for those things.'' *Id.* at 610–11. Superior II's counsel then explained that he understood ''that this may be a bifurcated issue where there's a notice issue on acceptance of responsibility [and] corrective action,'' but ''no notice issue on what's in the Government's Pre-hearing statement but [was] still being excluded from the record.'' *Id.* at 611. Superior II's counsel then represented that with respect to ''the matter of what is in the Government's Pre-hearing Statement . . . Respondent has an extensive proffer about that for the record which would address a wide variety of things.'' *Id.* Continuing, Superior II's counsel explained that his previous statements were his ''legal argument rather than the factual proffer'' and then asked that he ''be

[50] While the ALJ then offered the Government the opportunity to respond to the motion, the Government chose not to. Tr. 607.

permitted to actually make the detailed proffer.'' *Id.* at 611–12.

The ALJ rejected the request, explaining that ''[y]ou were permitted to do so. That's what the Pre-hearing Statement was for.'' *Id.* at 612. Continuing, the ALJ explained that the record now reflected Respondent's proffer and ''that the detailed proffer that you're describing was appropriate and was not provided to me in a timely fashion. And I believe that was a strategic decision of prior counsel.'' *Id.*

The Government then rested. *Id.* at 612–13. Thereafter, Superior II's counsel sought to call Mr. Obi. *Id.* at 614. The ALJ denied the request for the reasons he had previously explained.

Discussion

Under the CSA, ''[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In the case of a retail pharmacy, which is deemed to be a practitioner, *see* id. § 802(21), Congress directed the Attorney General to consider the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id.

''[T]hese factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether'' to suspend or revoke an existing registration. *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482.[51]

Under the Agency's regulation, ''[a]t any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to . . . 21 U.S.C. 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is confined to factors two and four.[52] For reasons explained below, I find the Government's evidence insufficient to establish that Respondents' pharmacists violated their corresponding responsibility when they dispensed the prescriptions at issue. However, I find that the Government has established by substantial evidence that Respondents have failed to maintain accurate records, as well as other violations, and that it has thus established that Respondents have committed acts which render their registrations ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Because I further find that Respondents did not properly disclose in advance of the proceeding their proposed evidence as to any remedial measures, I conclude that Respondents have not rebutted the Government's *prima facie* showing. I will therefore order that each Respondent's registration be revoked and that any pending application be denied.

Factors Two and Four—The Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

The Dispensing Allegations

''Except as authorized by'' the CSA, it is ''unlawful for any person [to] knowingly or intentionally . . . manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.'' 21 U.S.C. 841(a)(1). Under the Act, a pharmacy's registration authorizes it ''to dispense,'' *id.* § 823(f), which ''means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner.'' *Id.* § 802(10).

The CSA's implementing regulations set forth the standard for a lawful controlled substance prescription. 21 CFR 1306.04(a). Under the regulation, ''[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' *Id.* Continuing, the regulation provides that:

[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, *but a corresponding responsibility rests with the pharmacist who fills the prescription.* An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person *knowingly filling* such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.[53]

[51] In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's or applicant's misconduct. *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821. Likewise, findings under a single factor can support the denial of an application.

[52] As to factor one, there is no evidence that the Florida Department of Health has either made a recommendation to the Agency with respect to either Respondent, or taken any disciplinary action against either Respondent. *See* 21 U.S.C. 823(f)(1). However, even assuming that each Respondent currently possesses authority to dispense controlled substances under Florida law and thus meets a prerequisite for maintaining its registration, this finding is not dispositive of the public interest inquiry. *See Mortimer Levin,* 57 FR 8680, 8681 (1992) (''[T]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.''). Accordingly, this factor is not dispositive either for, or against, the revocation of each Respondent's registration. *Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

As to factor three, I acknowledge that there is no evidence that either of the Respondents, or Mr. Obi-Anadiume, or any of the Respondents' pharmacists, has been convicted of an offense under either federal or Florida law ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

As to factor five, no evidence was offered with respect to it.

[53] As the Supreme Court has explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)).

Id. (emphasis added).

As the Agency has made clear, to prove a violation of the corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp.,* 80 FR 28667, 28669 (2015). Thus, the Government can prove a violation by showing either: (1) That pharmacist filled a prescription notwithstanding his/her actual knowledge that the prescription lacked a legitimate medical purpose; or (2) that the pharmacist was willfully blind (or deliberately ignorant) to the fact that the prescription lacked a legitimate medical purpose. *See id.* at 28671–72. As to establishing that a pharmacist acted with ''willful blindness, proof is required that: '(1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.'' *Id.* at 28672 (quoting *Global-Tech Appliances, Inc.,* v. *SEB S.A.,* 563 U.S. 754, 769 (2011)).

Here, the Government makes no claim that any of Respondents' pharmacists dispensed the prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, relying primarily on *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62316, 62341 (2012), the Government argues that a pharmacist violates the corresponding responsibility rule when he/she dispenses a controlled substance prescription ''in the face of a red flag (*i.e.*[,] a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription) unless he . . . takes steps to resolve the red flag and ensure that the prescription is valid.'' Gov. Post-Hrng. Br. 16. The Government argues that each Respondent's pharmacists violated this regulation by filling oxycodone prescriptions which presented various ''red flags'' which were never resolved. Gov. Post-Hrng. Br. 15–18. Noting that its pharmacy expert gave ''unrefuted testimony,'' the Government argues that ''[a]ll of the prescriptions discussed by [its Expert] we[re] for highly abused drugs such as oxycodone and hydromorphone'' and ''contained one or more of'' some six ''red flags.'' *Id.* at 17. It further argues that the Expert ''testified that no evidence could be found to show the red flags had been resolved prior to dispensing.'' *Id.*

As proof for its assertion that the red flags were not resolved, the Government points to its Expert's testimony ''that, in the practice of pharmacy, a red flag which is resolved must be documented and that the documentation should be placed on the prescription itself.'' *Id.* It further notes that the prescriptions contained no notations showing that the pharmacists resolved the red flags (with the exception of the address stickers that were placed on the prescriptions). It further contends that ''[t]o the extent the Respondents may argue that [their] practice was to place such documentation elsewhere, that argument flies in the face of evidence showing that [the pharmacies] habitually corrected 'mistakes' related to prescriptions on the prescriptions themselves,'' such as the missing patient addresses and the instance in which a pharmacist marked on the prescription that it had only been partially filled. *Id.*at 17–18.

Here, I assume that the red flags with respect to each prescription or the convergence of red flags—as there were typically multiple red flags associated with each prescription—establishes that the pharmacists ''subjectively believed that there was a high probability'' that the various prescriptions lacked a legitimate medical purpose.[54] I nonetheless conclude that the Government has failed to put forward sufficient evidence to establish that the pharmacists failed to resolve the various red flags (*i.e.,* that they deliberately failed to avoid learning of the fact that the prescriptions lacked a legitimate medical purpose).

As noted above, as proof that the pharmacists failed to resolve the red flags, the Government relies solely on the absence of such documentation on the prescriptions themselves and the Expert's testimony that it is the custom in pharmacy practice to document the resolution of a red flag on the prescription. Yet as the Expert conceded, no provision of the Controlled Substances Act, DEA regulations, Florida law, or the Florida Board of Pharmacy's regulations requires that a pharmacist document the resolution of red flags on the prescription itself.[55] While it would be reasonable to draw an adverse inference that a pharmacist failed to resolve a red flag (or flags) from the failure to document the resolution in any manner, the Government offered no evidence that the DIs *even asked* the pharmacists at either Respondent if they documented their resolution of red flags, and if so, where they did so.

Here, a regulation of the Florida Board of Pharmacy (then in effect) specifically required that ''[a] patient record system . . . be maintained by all pharmacies for patients to whom new or refill prescriptions are dispensed'' and that the ''system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing.'' Fla. Admin. Code 64B–16–27.800. This rule also required that the pharmacy maintain ''[a] list of all new and refill prescriptions obtained by the patient at the pharmacy . . . during the two years immediately preceding the most recent entry'' and include the ''prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber.'' *Id.* The rule further required that the record include the ''[p]harmacist['s] comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' *Id.* And the rule also required that the pharmacist make ''a reasonable effort . . . to obtain from the patient . . . and record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs . . . being used by the patient which may relate to prospective drug review.'' *Id.* Finally, the rule required that ''[t]he pharmacist . . . record any related information indicated by a licensed health care practitioner.'' *Id.*[56]

[54] All red flags do not have the same hue, and as the Supreme Court's decision in *Global-Tech* makes plain, proof that a pharmacist dispensed a controlled substance prescription without resolving a red flag which only created a ''reasonable suspicion'' that the prescription lacked a legitimate medical purpose, is not enough to establish that a pharmacist acted with the requisite scienter. However, where there are multiple red flags, none of which alone would establish the requisite scienter, the combination of red flags may well create a subjective belief that there is a high probability that a prescription lacks a legitimate medical purpose.

[55] While it may be customary in the profession to document the resolution of a red flag on the prescription itself, that does not make it improper to document the resolution someplace else. Moreover, while evidence of a custom certainly has probative value, it is not conclusive proof. *See Sorrels* v. *NCL (Bahamas) Ltd.,* 796 F.3d 1275, 1282 (11th Cir. 2015) (''[E]vidence of custom within a particular industry, group, or organization is admissible as bearing on the standard of care in determining negligence. Compliance or noncompliance with such custom, though *not conclusive on* the issue of negligence, is one of the factors the trier of fact may consider in applying the standard of care.'') (emphasis added) (quoting *Muncie Aviation Corp.* v. *Party Doll Fleet, Inc.,* 519 F.2d 1178, 1180–81 (5th Cir. 1975)); II Wigmore, Evidence, § 379, at 403 (Tillers rev. ed. 1983) (explaining that with respect to evidence of custom or usage of trade, ''the question is not whether the offered instances fully prove the custom alleged, but merely whether they are receivable as having probative value'').

[56] This rule remains in effect today; however, the rule now requires that the information be

Continued

Of further note, the Board of Pharmacy's rules require that a pharmacist ''review the patient record and each new and refill prescription presented for dispensing in order to promote therapeutic appropriateness.'' Fla Admin Code r. 64B16–27.810. This rule specifically requires that a pharmacist identify such issues as: ''[o]ver-utilization,'' ''[t]herapeutic duplication,'' ''[d]rug-drug interactions,'' ''[i]ncorrect drug dosage,'' and ''[c]linical abuse/misuse.'' *Id.*

On cross-examination, the Expert testified that he asked DEA ''for complete profiles on all these patients'' but was told to look at only the prescriptions. Tr. 247; *see also id.* at 324–25 (testimony of Expert that he had asked for patient profiles for the Superior II patients and was told not look at them, although it was unclear whether he actually received them). He further acknowledged that a patient profile would show a patient's complete history of the prescriptions filled at the pharmacy during the period for which it was run, as well as whether the patient was opioid naïve or tolerant. *Id.* at 325. While subsequent testimony suggests that the Agency's Investigators did not obtain the patient profiles (at least with respect to Superior II) [57] but only state PMP reports, both the Board's regulation and the Expert's testimony establish that the patient profiles were relevant evidence in assessing whether Respondents' pharmacists had resolved the red flags, whether they contained such proof or not.

The Government nonetheless argues that it had no obligation to produce the patient profiles and that the Respondents' position would force the Government to ''search the entire universe for exculpatory evidence.'' Gov. Mot. to Supplement the Record, Strike Respondent's Untimely Exceptions, . . . Or, In the Alternative, Respond to Exceptions, at 15. It further argues that it is entitled to an adverse inference that Respondents' pharmacists did not resolve the various red flags because such evidence, if it does exist, is ''under the complete control of the Respondent'' and ''not DEA'' and Respondent ''fail[ed] to produce'' it. *Id.* (citing *Int'l Union, UAW* v. *NLRB,* 459 F.2d 1329, 1336 (D.C. Cir. 1972)).

As for the contention that Respondents' position would force the Government to ''search the entire universe for exculpatory evidence,'' it does no such thing. Indeed, the Government ignores that its own Expert sought to review the patient profiles and that the Board of Pharmacy's rules mandate that a pharmacist review the patient's profile as part of the prospective drug use review which is required before filling a prescription. Unexplained by the Government is why it would be improper for pharmacists to document their resolution of a red flag in the patient profile given that the Board's rules required (and still require) that a pharmacist document his/her ''comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug,'' as well as ''any related information indicated by a licensed health care practitioner'' in that record.

Of further consequence, the Government produced no evidence establishing when the various patients first filled prescriptions at Respondents for the drugs in the prescriptions at issue here. Unexplained by the Government is why, if the red flags associated with a specific patient and prescription had been previously resolved and this was documented in the patient profile, the pharmacists were nonetheless required to document this on subsequent prescriptions.

I also reject the Government's contention that it is entitled to an adverse inference based on the failure of Respondents to produce any evidence showing that they resolved the red flags. Under the adverse inference rule, if a party has evidence within its control that ''would in fact strengthen [its] case, [it] can be expected to introduce it even if it is not subpoenaed.'' *Int'l Union,* 459 F.2d at 1338. Be that as it may, while the patient profiles remained within Respondents' control, *International Union* itself recognizes that ''if a party has good reason to believe his opponent has failed to meet [its] burden of proof, [it] may find no need to introduce his strong evidence.'' *Id.*

Here, the Government has the burden of proof. *See* 21 CFR 1301.44(d) & (e). While it may be that there is nothing in the patient profiles which would have been favorable to Respondents, given that the Government's Expert acknowledged the relevance of these records and the scope of the information required by the Board's rule to be maintained in them, requiring the Government to put forward evidence as to whether the patient profiles show that the various red flags were not resolved, is not fairly described as requiring it ''to search the entire universe for exculpatory evidence.'' To the contrary, obtaining and reviewing patient profiles would seem to be fundamental to conducting an adequate investigation of the dispensing allegations.

As further support for its contention that the absence of documentation on the prescriptions is proof that the red flags were not resolved, the Government points to the evidence showing that where the physicians failed to include the patients' address, the pharmacists placed address stickers on the prescriptions. It also points to a single prescription, which was partially filled, and that the pharmacist documented this on the face of the prescription.

Yet Florida law expressly required (and still requires) that a patient's address ''appear on the face of the prescription.'' Fla. Sta. Ann. § 893.04(c); *see also* 21 CFR 1306.05(a) (''All prescriptions for controlled substances . . . shall bear the full name and address of the patient[.]'').[58] As for the partially filled prescription, a DEA regulation requires that the pharmacist ''make a notation of the quantity supplied on the face of the written prescription . . . or in the electronic prescription record.'' 21 CFR 1306.13(a). By contrast, no law or rule requires the documentation of the resolution of a red flag to be placed on the prescription itself. Finally, it bears repeating that there is no evidence in the record that the Investigators even asked Respondents' pharmacists, as a general matter, if they resolved red flags presented by controlled substance

maintained for a period of four years preceding the most recent entry.

[57] With respect to Superior I, a DI testified that he believed that digital evidence was collected. Tr. 372.

[58] Quoting 21 CFR 1306.05(a), the Government suggests that prescriptions were ''[d]ispensed in an [i]mproper manner.'' Gov. Post-Hrng. Br. 18. The Government then states: ''[a]s evidenced [b]y many of the prescriptions themselves for both Superior I and II, prescriptions were repeatedly issued absent a patient address.'' *Id.* The Government, however, offers no further explanation as to why Respondents violated federal law by filling the prescriptions given that they contain address stickers for the patients.

Of note, the DEA Office of Diversion Control maintains a Web page of ''Questions & Answers'' pertaining to prescriptions. *See http://www.deadiversion.usdoj.gov/faq/prescriptions.htm.* One of the questions is: ''What changes may a pharmacist make to a prescription written for a controlled substance in schedule II?'' *Id.* at 2. In its answer, the Office of Diversion Control noted a conflict between its previous policy and a statement made in a 2007 rulemaking entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances;* the answer further explained that the Agency ''plans to resolve this matter through a future rulemaking.'' *Id.* The Answer then advised that ''[u]ntil that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber.'' *Id.* Because the Government has produced no evidence that Florida law, the Board of Pharmacy's regulations, or the Board's policy prohibited the pharmacists from adding the patient's address to the prescriptions, I reject the Government's suggestion.

prescriptions, and if so, how they documented having done so.[59]

Accordingly, I find that the Government's allegations that Respondents' pharmacists violated 21 CFR 1306.04(a) and Fla. Stat. Ann. § 465.016(1)(s)) when they dispensed controlled substance prescriptions without resolving the red flags presented by the prescriptions are not supported by substantial evidence.[60]

The Audits and Recordkeeping Allegations

The evidence nonetheless shows that both Respondents violated the CSA by failing to maintain and/or properly maintain required records. With respect to Superior I, the evidence is particularly egregious, as an audit conducted by Agency Investigators found that the pharmacy had shortages of 15,560 du of oxycodone 30 mg and 11,951 du of hydromorphone 8 mg. In addition, Superior I was short 946 du of hydromorphone 4 mg, 864 du of methadone 10 mg, 474 du of morphine sulfate 100 mg ER, and 447 du of morphine sulfate 30 mg ER. Thus, Superior I was short more than 30,000 du of highly abused controlled substances. And while Superior II had only a small shortage of a single drug, it had substantial overages in several drugs, including 2,576 du of hydromorphone 8 mg and 1,189 du of oxycodone 30 mg.

''Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.'' *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Fred Samimi,* 79 FR 18698, 18712 (2014) (finding where physician ''had shortages totaling more than 40,000 dosage units'' of various drugs that his ''inability to account for this significant number of dosage units creates a grave risk of diversion,'' and that ''even were there no other proven violations, the audit results alone are sufficient to . . . establish[] that [physician's] registration[] 'would be inconsistent with the public interest''') (citations omitted).

During the hearing, Respondents raised various challenges to the validity of the audits. With respect to the Superior I audit, Respondent's counsel attempted to impeach the DI's result by using a document he described as ''scratch paper'' which, according to his representation, had been included among the documents returned to Respondents on the CD and which listed the DEA 222 forms for Superior I's morphine sulfate orders; Respondent's counsel further represented that when he added up the orders, he got a number of 7,200 du. Tr. 395.

I need not decide whether the ALJ erred when he barred Superior I's counsel from using this document to impeach the DI, Tr. 394–95, because Respondent did not properly preserve the claim of error. Notably, Respondent's counsel did not seek to submit the document even as a rejected impeachment exhibit, and in its Post-hearing Brief, Respondent did not specifically identify this ruling as being in error. Indeed, while in its Post-hearing Brief, Superior I proposes as a factual finding that it ''proffered Exhibits 3 through 9 including invoices and other records that demonstrate errors in the DEA audit which resolve the alleged inventory *overages,''* Resp. Post-Hrng. Br. 9 (emphasis added), with respect to Superior I, the gravamen of the Government's audit allegation was that it had *shortages* of multiple drugs.[61] Moreover, Exhibits 3 through 9, which comprise nearly 1500 pages of assorted documents, and which purportedly include relevant records for each of the audited drugs, are just that—raw documents, with no accompanying explanation or calculations showing why the Government's audit results are in error.[62]

Respondent also questioned the validity of the audits on the ground that while the DIs could have verified their calculations as to the level of Respondents' purchases of the drugs by obtaining data from the Agency's ARCOS database, they ''willfully chose to ignore that evidence which would have demonstrated the accuracy of the pharmacies' records with respect to [their] purchases.'' *Id.* at 20. Contrary to Respondent's understanding, one of the purposes of an audit is to determine *whether the audited party* is maintaining ''a complete and accurate

[59] The Government also alludes to testimony by its Expert to the effect that he was shown partial medical records for the patients and that he found no evidence in these records ''that any conversation had taken place between the prescriber and the Respondents' pharmacist.'' Gov. Post-Hrng. Br. 17 n.10. None of these records are in evidence, and thus, there is no evidence establishing when the patients first saw the physicians and whether there was any communication between the pharmacists and prescribers at that time. In any event, there is no evidence in the record establishing that a physician has an obligation under the standard of care to document phone calls from a pharmacist questioning his prescription. Accordingly, I place no weight on this testimony.

[60] As found above, on various occasions, the Government elicited testimony from its Expert, over Respondents' objections, to the effect that some of the prescriptions presented red flags that could not be resolved. While the Government made no argument based on this testimony in its Post-hearing Brief, the ALJ made multiple findings that several of the prescriptions presented red flags that could not be resolved. *See* R.D. 80–81 (FoF#s 9, 10). Moreover, in its Response to Respondent's Exceptions, the Government invokes this evidence. *See* Gov. Response to Resp.'s Exceptions, at 14 (''Notwithstanding the fact that Mr. Parrado credibly testified that he discovered red flags which, in his opinion, were unresolvable . . . Respondents are now arguing for a new rule that requires the Government to prove a negative.'') (citing Tr. 145–46, 289–90).

While in the Show Cause Orders, the Government made conclusory allegations to the effect that the Respondents' ''pharmacists dispensed controlled substances when they knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose,'' ALJ Ex. 1, at 2 (No. 15–6), which implies that the red flags could not be resolved, the Government never identified a specific prescription in either Show Cause Order or any of its Prehearing Statements that could not be resolved. As explained previously, while the ALJ overruled Respondents' objections, the correct standard is not whether the ALJ wanted to know the answer to the Government's question, Tr. 287, but whether Respondents knew ''what conduct was being alleged and ha[d] a fair opportunity to present [their] defense.'' *Duane* v. *DOD,* 275 F.3d 988, 995 (10th Cir. 2002) (quoting *Facet Enters., Inc.,* v. *NLRB,* 907 F.2d 963, 972 (10th Cir. 1990). *See also Pergament United Sales,* 920 F.2d at 135 (''Notice does not mean a complaint necessarily must state the legal theory upon which the General Counsel intends to proceed. Instead notice must inform the respondent of the acts forming the basis of the complaint.''); *see also id.* (''The primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior.'').

Because the Government never alleged that any of the prescriptions could not be resolved, and Respondents objected to this line of inquiry, there is no basis for a finding of litigation by consent. Accordingly, I do not consider the testimony that the some of the prescriptions presented unresolvable red flags.

[61] Likewise, even assuming the correctness of Superior I's counsel's representation that when he added up the morphine sulfate orders, he got ''a number of 7,200,'' Tr. 395, he made no proffer as to errors with respect to the audit results for oxycodone 30 mg and hydromorphone 8 mg, which found massive shortages.

[62] It is noted that Respondents attached, as supplements to their untimely filed Exceptions, charts which purport to show audit results for both pharmacies which are dramatically different from those found by the Government. See Resp. Exceptions, at Appendices A & B. Respondents offered no foundation for consideration of the charts, and in any event, the charts are not properly considered as newly discovered evidence.

Furthermore, while throughout the proceeding, Respondents have argued that their due process rights have been violated because the Agency's Lead Investigator ''unlawfully retained'' records seized pursuant to the Administrative Inspection Warrants for some 611 days, Resp. Post-Hrng. Br. 18, Respondents were provided with the records on or about the same day they were served with the Show Cause Orders, which made specific allegations as to the audits. Thus, Respondents had approximately 80 days from the date they were informed of the allegations to the date on which they were required to file their Prehearing Statements to investigate the allegations pertaining to the audits and prepare a defense.

While Respondents argue that ''[t]he first access [they] had to what may or may not be all of the evidence was on the day that DEA served its Order to Show Cause,'' Resp. Post-Hrng. Br. 19, they did not identify any records that were necessary to complete their audits which were not provided to them when their records were returned.

record of each [controlled] substance . . . received, sold, delivered, or otherwise disposed of by him.'' *See* 21 U.S.C. 827(a)(3); *see also id.* at § 827(a)(1) (requiring registrants to ''make a complete and accurate record of all stocks . . . on hand'' when ''first engag[ing] in the . . . dispensing of controlled substances, and every second year thereafter''). Putting aside that Respondents produced no evidence showing discrepancies between the DIs' calculations as to the quantities of the drugs received by them and the distributions as reported by their suppliers to the ARCOS system, the DIs were entitled to rely on the records provided by Respondent in response to the warrant. Given that ARCOS data is compiled from distribution reports submitted by manufacturers and distributors, and Respondents were not required to file reports to ARCOS, *see* 21 CFR 1304.33(c), the DIs had no obligation to cross-check their calculations with ARCOS data.

Respondent Superior II questioned the validity of the audit pertaining to it, on the ground that the DI based her initial inventory figures on a perpetual inventory which Respondent is not lawfully required to maintain. However, the DI testified multiple times that she asked for an actual physical count which was at least six months old and used what Superior II gave her. Tr. 491–92. I thus reject Respondent's challenge to the findings of the audit of Superior II, which establishes that it had overages in several drugs.[63]

I thus find that both pharmacies failed to maintain complete and accurate records as required by 21 U.S.C. 827(a)(1) & (3). While this finding alone supports the conclusion that each pharmacy has committed such acts as to render its continued registration ''inconsistent with the public interest,'' *see* 21 U.S.C. 824(a)(4), the scope of the shortages of oxycodone 30 mg and hydromorphone 8 mg found during the audit of Superior I supports a sanction of revocation. *See Samimi,* 79 FR at 18712.

The Government further alleges that Respondents failed to properly complete various schedule II order forms. More specifically, with respect to Superior I, the Government's evidence included an Order Form for oxycodone 30 on which the National Drug Code was changed. GX 5, at 1 (No. 15–6). However, while the DI testified that ''any alteration or any erasure or change of description'' should result in the form not being used,'' the applicable regulation actually states that the order ''*must not be filled* if . . . [t]he order shows any alteration, erasure, or change of any description.'' 21 CFR 1305.15(a) (emphasis added). Thus, the regulation is not fairly read as imposing liability on Superior I for changing the National Drug Code.

The DI also testified that a second order form was not filled out properly, because ''information in regard to the number of package[s] receive [sic] . . . was omitted.'' Tr. 384. However, the Government offered no evidence that any portion of the two orders listed on the form were filled. While DEA's regulation states that ''[t]he purchaser must record on Copy 3 of the . . . 222 the number of commercial or bulk containers on each item and the dates on which the containers are received by the purchaser,'' 21 CFR 1305.13(e), the Government points to no provision which requires, where no portion of a line entry has been filled by the expiration of the 60-day period in which the Order Form is valid, *id.* § 1305.13(b), the purchaser to notate on the form that no portion of that entry was received.[64]

The Government made similar claims with respect to Superior II. For example, it identified the first two pages of GX 6 (No. 15–7) as examples of Order Forms that were not properly completed because the second entry on each form did not list the number of packages received and the date received. Putting aside that these two documents bear the exact same serial number, here again, the Government put forward no evidence that any portion of the order listed in the second line item was filled. While here too, this DI insisted that ''after 60 days, the 222 is invalid'' and that Respondent ''should go back and put a zero and the date they put the zeros'' on the form, as explained above, the regulations do not so require. And while the DI also asserted that the *Pharmacist's Manual*—which does not have the force and effect of law anyway—instructs pharmacists to do this, the *Manual* actually states that ''[w]hen the items *are received,* the pharmacist must document on the purchaser's copy (copy three) the actual number of packages received and the date received'' and nothing more. DEA, *Pharmacist's Manual—An Informational Outline of the Controlled Substances Act* 23 (Rev. ed. 2010).

While the DI further identified other Order Forms in this Exhibit which she alleged were not properly completed, she did not identify a single instance in which a line item had actually been shipped to Respondent and the entry had not been made. Indeed, with respect to the Exhibit, the only violations the DI identified were that the forms were copies and not the original. Tr. 474–75, 521. Under a DEA regulation, ''[t]he purchaser must retain Copy 3 of each executed DEA Form 222.'' 21 CFR 1305.13(a). Standing alone these violations would be of minimal consequence.

The evidence further showed that while Superior II used the electronic Controlled Substances Ordering System to purchase controlled substances, it did not comply with 21 CFR 1305.22(g). Under this provision, ''[w]hen a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record *must be electronically linked to the original order and archived.''* 21 CFR 1305.22(g). The evidence shows that Respondent's pharmacists would print out a copy of the electronic order form and by hand, notate in the boxes in which the Supplier is to list the ''Packages Shipped'' and the ''Date Shipped,'' the number of packages received and the date received. *See generally* GXs 7 & 10; Tr. 551. According to the DI, when she asked Mr. Majed (one of Superior II pharmacists), how he documented the pharmacy's receipt of the drugs, the pharmacist explained that he did not go back into the CSOS because ''he wasn't aware that he had to do that.'' Tr. 554.

The record thus supports the conclusion that Superior II's receipts were not documented electronically and were not linked to the original order. Thus, I conclude Superior II violated 21 CFR 1305.22(g) with respect to the numerous electronic orders it placed.

The DI also testified that Mr. Majed represented that he had a key which is required under the Agency's regulations for placing electronic orders through the CSOS. Tr. 557–58. Under DEA's regulation, a person must ''obtain a CSOS digital certificate from the DEA Certification Authority to sign electronic orders for controlled substances.'' 21 CFR 1311.10. However, a person is eligible to obtain a CSOS digital certificate only if he/she: (1) is the person who ''signed the most recent registration application or renewal application,'' (2) is ''a person authorized to sign a registration application,'' or (3) has been ''granted power of attorney by [the] registrant to sign orders for one or more schedules of controlled

[63] While Superior II also argues that DEA failed to consider ARCOS data in auditing it, I reject the argument for the same reasons that I rejected the argument with respect to Superior I's.

[64] While the purchaser's copy 3 of the form includes columns ''To Be Filled In By Purchaser'' in which the purchaser lists the ''No. of Packages Received'' and the ''Date Received'' for each line item, *see* GX 5 (No. 15–6), if no packages of that item have been received, then there is no date on which they were received.

substances.'' *Id.* DEA's regulations further provide that ''[o]nly the certificate holder may access or use his or her digital certificate and private key,'' and ''[a] certificate holder must ensure that no one else use the private key'' and ''prevent unauthorized use of that private key.'' *Id.* § 1311.30. According to the DI, after her conversation with Mr. Majed, she determined that only Mr. Obi, Respondent's owner, and Ms. Minozzi, another pharmacist, had been issued CSOS keys. Accordingly, I conclude that Respondent violated 21 CFR 1311.30(a) and (c).

Accordingly, I conclude that the evidence with respect to factor four—Respondents' compliance with applicable laws related to controlled substances—establishes that each Respondent ''has committed such acts as would render [its] registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

Sanction

Under Agency precedent, where, as here, ''the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must ' ''present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility carried by such a registration.'' ' '' *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels,* 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[ ]'' in the public interest determination).

While a registrant must accept responsibility and demonstrate that it will not engage in future misconduct in order to establish that its continued registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Paul Weir Battershell,* 76 FR 44359, 44369 (2011) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and ''manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant''); *Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

The Agency has also held that '' '[n]either *Jackson,* nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked.' '' *Gaudio,* 74 FR at 10094 (quoting *Southwood,* 72 FR at 36504); *see also Robert Raymond Reppy,* 76 FR 61154, 61158 (2011); *Michael S. Moore,* 76 FR 45867, 45868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36503). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoptions of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

Here, the record contains no evidence that the principals of either Respondent acknowledge its misconduct. So too, the record contains no evidence that either Respondent has undertaken any remedial measures.

Respondents attribute this to the ALJ's ruling barring Mr. Obi (Respondents' owner) from testifying. They argue that the ALJ's ruling denied them their right to due process and a fair hearing under the Administrative Procedure Act. *See* Resp. Post-Hrng. Br. 23 (citing, *inter alia, Oshodi* v. *Holder,* 729 F.3d 883, 889 (9th Cir. 2013) (en banc); *Block* v. *SEC,* 50 F.3d 1078, 1085 (D.C. Cir. 1995); 21 [sic] U.S.C. 556). Tallying up the number of each party's objections which the ALJ overruled versus those he sustained, as well as the number of times the ALJ, *sua sponte,* instructed a witness not to answer a question, they assert that ''[t]his unmistakable pattern reflects the [ALJ's] clear bias against Respondents.'' *Id.* at 27. As additional grounds for their contention that the ALJ was biased, they assert that he ''refused to require the DEA to obey the order of the Federal Magistrate Judge.'' *Id.* at 34.

As for their claim of bias, none of their assertions establish bias. As found above, while several of the ALJ's rulings on objections were erroneous, many of them were not, and some of Respondents' objections were clearly lacking in merit. In any event, ''judicial rulings alone almost never constitute a valid basis for a bias or partiality motion.'' *Liteky* v. *United States,* 510 U.S. 540, 555–56 (1994) (citing *United States* v. *Grinnell Corp.,* 384 U.S. 563, 583 (1966)).

As for the contention that bias is established by the ALJ's refusal to require the DI to obey the Federal Magistrate Judge's order, Respondents point to no provision of law which grants an Administrative Law Judge authority to order the Government to comply with an order of a Federal Magistrate Judge.[65] A Magistrate Judge has authority to ensure compliance with his orders, including the power to hold a disobeying party in contempt. *See* 28 U.S.C. 636. Respondents offer no explanation for why they did not seek an order compelling the return of the documents from the Magistrate Judge who approved the warrant. I thus reject Respondents' claim that the ALJ's ruling on Mr. Obi's testimony should be rejected on the ground of bias.[66] Indeed, Respondents self-refute their claim of bias when they argue that ''[*t*]*he real reason* that the ALJ refused to let Mr. Obi testify was because he felt like Respondents' counsel had not adequately complied with the

[65] Respondents do not identify what orders the DI violated. If Respondents mean the administrative inspection warrants, the language of the warrants only provided for a return of the warrant to the court and an accounting of the property seized. Resp.'s Post-Hrng. Br., at Attachments 1 and 2. The warrants contained no provision requiring the return of the seized property, and Respondents point to no further orders by the court to return the records.

[66] Respondents further assert that the ALJ's ''general bias . . . finds its roots in'' what they characterize as ''the Administrator's public scolding of the ALJ in *Clair L. Pettinger, M.D.,* 78 [FR] 61591 (2013), for requiring the DEA to follow the procedural rules of the Agency and for his interpretation of the law.'' *Id.* at 35. Not only is Respondents' explanation of *Pettinger* counterfactual (both the pleading burden imposed by the ALJ and his interpretation of factor two were inconsistent with agency precedent), they cite no authority for their theory. Beyond that, Respondents ignore the extensive protections provided to ALJs under federal law to ensure decisional independence, including that they are not subject to performance appraisals, 5 U.S.C. 4301(2)(D), their pay is set by OPM independent of any evaluation by the Agency, *id.* § 5372, and they are subject to discipline only upon a showing of good cause by the MSPB. *Id.* § 3105.

disclosure requirements of the ALJ's prehearing order.'' Resp. Exceptions, at 24 (emphasis added).

Respondents thus assert that the ALJ erred in barring Mr. Obi from testifying because he was an interested person within the meaning of the APA. That Mr. Obi is an interested person is hardly disputable. However, while an interested person has a right to participate in a proceeding, that right is subject to the reasonable procedural rules of the Agency and rulings of the ALJ. *See, e.g.,* 5 U.S.C. 556(c) (''Subject to published rules of the agency and within its powers, employees presiding at hearings may . . . regulate the course of the hearing.''); 21 CFR 1316.58(a) (''The presiding officer may direct that summaries of the direct testimony of witnesses be prepared in writing and served on all parties in advance of the hearing.'').

Here, in his Orders for Prehearing Statements, which were issued more than one month before Respondents' Prehearing Statements were due, the ALJ specifically warned Respondents that if their ''corporate representative intends to testify, the representative must be listed as a witness, and a summary of anticipated testimony as described below must be provided.'' ALJ Ex. 5, at 2 (No. 15–6); ALJ Ex. 6, at 2 (No. 15–7). The Orders for Prehearing Statements also cautioned Respondents that their summaries of testimony must ''indicate clearly each and every matter as to which Respondent[s] intend[ ] to introduce evidence in opposition'' and that ''[t]he summaries are to state what the testimony will be rather than merely listing the areas to be covered.'' ALJ Ex. 5, at 2 (No. 15–6); ALJ Ex. 6, at 2 (No. 15–7). And finally, the Orders for Prehearing Statements further warned ''that testimony not disclosed in the prehearing statements or pursuant to subsequent rulings is likely to be excluded at the hearing.'' ALJ Ex. 5, at 2 (No. 15–6); ALJ Ex. 6, at 2 (No. 15–7).

Respondents thus had fair notice of the steps they were obligated to take to present Mr. Obi's testimony. While Respondents represented in their Prehearing Statements that they intended to call ''[a]ny and all witnesses identified in the Government's Prehearing Statement[s] in th[ese] matter[s],'' and the Government identified Mr. Obi as a potential witness therein, Respondents entirely failed to provide a summary of the testimony they intended to elicit from him. ALJ Ex. 9, at 4 (No. 15–6); ALJ Ex. 12, at 4 (No. 15–7).

While at the hearing Respondents asserted that there would be no prejudice to the Government because ''the summary of Mr. Obi's testimony'' was ''covered sufficiently'' by the Government in its Prehearing Statements, the Government's summary of Mr. Obi's anticipated testimony was confined to questioning him about past acts. Tr. 597–98; *see also* ALJ Ex. 7, at 6–7 (No. 15–6); ALJ Ex. 7, at 8–9 (No. 15–7). Indeed, Respondents' Counsel conceded that he intended to elicit testimony from Mr. Obi as to the corrective actions Respondents had undertaken and that this raised a notice issue. *Id.* at 611. Moreover, at no point prior to the hearing did Respondents provide notice to the Government that *any* of their proposed witnesses would testify regarding any corrective actions undertaken by the pharmacies.[67] *See* ALJ Ex. 9, at 4–6 (No. 15–6); ALJ Ex. 12, at 4–6 (No. 15–7). Thus, the ALJ did not abuse his discretion when he barred Mr. Obi from testifying.[68] *See Gunderson* v. *Department of Labor,* 601 F.3d 1013, 1021 (10th Cir. 2010).

Indeed, in their Post-Hearing Brief, Respondents argue that ''Mr. Obi's testimony could have been restricted to the issues discussed in the DEA's prehearing statement.'' Resp. Post-Hrng. Br. 24. However, as explained above, to rebut the Government's *prima facie* case, Respondents bore the burden of producing evidence as to their remedial measures. Thus, even if Mr. Obi had testified to those issues identified in the Government's Prehearing Statements and acknowledged Respondents' misconduct (as to those violations proven on the record), Respondents still would have failed to rebut the Government's *prima facie* case. Accordingly, even if it was error to bar Mr. Obi's testimony as to the issues discussed in the Government's Prehearing Statements, Respondents have not shown prejudice. *See Gunderson,* 601 F.3d at 1021 (An ALJ's error in excluding evidence must '' 'prejudicially affect a substantial right of a party' ''; ''[a]n error is prejudicial only 'if it can be reasonably concluded that with . . . such evidence, there would have been a contrary result.'''') (quoting *Sanjuan* v. *IBP, Inc.,* 160 F.3d 1291, 1296 (10th Cir. 1998)); *see also Air Canada* v. *Department of Trans.,* 148 F.3d 1142, 1156 (D.C. Cir. 1998) (''As incorporated into the APA, the harmless error rule requires the party asserting error to demonstrate prejudice from the error.'') (citing 5 U.S.C. 706). I thus reject Respondents' contentions with respect to the ALJ's ruling which barred Mr. Obi's testimony.[69]

[67] Respondents' reliance on *Oshodi* is not persuasive. Therein, the Ninth Circuit overturned a decision of the Board of Immigration Appeals (BIA), which affirmed a decision of an Immigration Judge that Oshodi, who was an applicant for asylum, was not credible. 729 F.3d at 885. Specifically, the court held that the Immigration Judge violated the applicant's right to due process ''by cutting off his testimony on the event of his alleged past persecution . . . that [were] the foundation of his'' claims, and denied his claims ''solely on the basis of [an] adverse credibility finding.'' *Id.*

Respondents also cite to *Kerciku* v. *INS,* 314 F.3d 913 (7th Cir. 2003), asserting that the ALJ violated their rights to due process by precluding them from putting on any case. Resp. Post-Hrng. Br. 2. In *Kericku,* the Seventh Circuit vacated a BIA decision which upheld an IJ's denial of applications for asylum, faulting the IJ for not allowing the applicants ''to make any presentation.'' 314 F.3d at 918.

Neither case, however, raised the issue of whether a party could be barred from putting on testimony when the party entirely failed to comply with an agency rule which requires disclosure of the substance of that testimony in advance of the proceeding to prevent prejudice. While Respondents also argue that the ALJ did not neutrally apply this rule, I have carefully reviewed the parties' respective Prehearing Statements, and conclude otherwise.

[68] In *Hatem M. Ataya, M.D.,* 81 FR 8221, 8243 (2016), I held that while the Agency's case law requires a respondent to acknowledge its misconduct and put on evidence of its remedial measures to rebut the Government's *prima facie* case, the Agency's cases do not require a respondent ''to admit to the allegations even before [it] even has the opportunity to challenge the Government's evidence.'' Thus, in *Attaya,* I held that a respondent's failure to acknowledge his misconduct in his prehearing statement could not bar him from introducing evidence of his remedial measures. *Id.* at 8242. However, in *Attaya,* I also held that because the respondent had not adequately disclosed ''with sufficient particularity'' his evidence of remedial measures, the testimony could nonetheless be barred.

Here, while Respondents failed to set forth any proposed testimony by Mr. Obi on the issue of acceptance of responsibility in advance of the hearing, this would not have been a bar to Mr. Obi's testimony as to Respondents' corrective measures, had such proposed testimony on the latter issue been disclosed in advance of the hearing. Just as in federal court, evidence that a respondent had undertaken remedial measures is not proof that it has engaged in culpable conduct. *Cf.* Fed. R. Evid. R.407.

While a respondent retains the right to challenge the allegations at the proceeding, when the Government serves a party with a show cause order, a respondent should assume that the Government has probable cause to support the allegations and a good faith basis for seeking the action (revocation or suspension) it proposes. A wise respondent conducts its own investigation to determine whether the allegations are true, and if they are, to then determine what measures are needed to correct the violations or offending practices. Thus, while a respondent retains the right to challenge the Government's evidence at the hearing, it is still properly charged with the obligation to disclose the remedial measures it has undertaken as a condition of being able to present such evidence at the hearing. Of course, where the Government fails to prove an allegation at the hearing, a respondent need not put on evidence of any corrective measures relevant to that allegation.

[69] As for Respondents' arguments with respect to the ALJ's ruling which precluded them from submitting their documentary evidence, *see* Resps.' Post-Hrng. Br. at 30–32, the ALJ's Prehearing Orders were clear enough that the documents had to be submitted in hard copy. Moreover, my holding that the Government has failed to prove any of the

Because Respondents failed to produce any evidence of remedial measures undertaken to address the numerous recordkeeping issues that I find proven on the record, I conclude that Respondents have not rebutted the Government's *prima facie* showing they have ''committed such acts as [to] render [their] registration[s] inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). And based on the substantial shortages found at Superior I, which supports the conclusion that it has major recordkeeping issues and/or has engaged in diversion, I conclude that revocation of its registration is warranted to protect the public interest.[70]

I acknowledge that Superior II's recordkeeping violations did not involve large shortages but rather overages. However, the pharmacy nonetheless failed to maintain complete and accurate records as required by the CSA, did not properly document its receipts on electronic order forms, and allowed an unauthorized person to access the electronic ordering system. In addition, the pharmacies have common ownership in that they are both owned by Mr. Obi. Thus, while the conduct proven with respect to Superior I is more egregious than that proved with respect to Superior II, given that Mr. Obi owns and controls each pharmacy, I conclude that revocation is warranted with respect to Superior II as well.[71]

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a)(4) and 823(f), as well as 28 CFR 0.100(b), I order that DEA Certificates of Registration BS9255274 and BS9699731 issued to Superior Pharmacy, L.L.C., be, and they hereby are, revoked. I further order that any application of Superior Pharmacy, L.L.C., to renew or modify either registration, be, and it hereby is, denied. This Order is effective June 17, 2016.

Dated: May 7, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–11550 Filed 5–17–16; 8:45 am]

BILLING CODE 4410–09–P

dispensing violations renders moot their contentions with respect to those exhibits that were relevant to those allegations.

As for the thousands of pages of exhibits that include records of Respondents' purchases and dispensings of the controlled substances audited by the Government, because Respondents failed to make an adequate proffer as to their audit results prior to the hearing, the ALJ did not abuse his discretion in declining to admit this evidence.

[70] Given the size of the shortages, the Agency's deterrence interests also support revocation.

[71] In numerous cases, DEA has held that where misconduct has previously been proved with respect to the owners, officers, or key employees of a pharmacy, the Agency can deny an application or revoke a registration of a second or subsequent pharmacy where the Government shows that such individuals have influence over the management or control of the second pharmacy. *See, e.g., Lawsons & Sons Pharmacy and Fenwick Pharmacy,* 48 FR 16140, 16141 (1983); *Orlando Wholesale, L.L.C.,* 71 FR 71555, 71557 (2006) (denying application noting evidence that ''one of Respondent's managing members had previously operated a business which distributed List I chemicals without a valid registration''); *Cf. 4 OTC, Inc.,* 77 FR 35031, 35035 (2012) (denying application for registration as List I chemical distributor where evidence showed that a person holding a 10 percent interest in applicant had been found by Canadian regulatory agency to have violated its List I regulations).